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DEPARTMENT OF ENERGY'S ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM

Y 4.G 74/7:EN 2/30

Department of Energy's Isotope Prod...

HEARING

BEFORE THE

ENVIRONMENT, ENERGY, AND
NATURAL RESOURCES SUBCOMMITTEE

OF THE

COMMITTEE ON
GOVERNMENT OPERATIONS
HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

FIRST SESSION

DECEMBER 6, 1993

Printed for the use of the Committee on Government Operations

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DEPARTMENT OF ENERGY'S ISOTOPE PRODUCTION AND DISTRIBUTION PROGRAM

MONDAY, DECEMBER 6, 1993

House of Representatives,
Environment, Energy,
and Natural Resources Subcommittee
of the Committee on Government Operations,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:03 a.m., in room 2247, Rayburn House Office Building, Hon. Mike Synar (chairman of the subcommittee) presiding.

Present: Representative Mike Synar.

Also present: Representatives Glenn English and William F. Clinger, Jr.

Staff present: Sandra Z. Harris, staff director; David M. Berick, professional staff member; Elisabeth R. Campbell, clerk; and Charli E. Coon, minority professional staff, Committee on Government Operations.

OPENING STATEMENT OF CHAIRMAN SYNAR

Mr. Synar. The subcommittee will come to order. The subcommittee meets today to continue hearings we began in August 1992 on the Department of Energy's Isotope Production and Distribution Program and the reliability of America's supply of isotopes for medical, research, and industrial purposes.

Given the arcane nature of this subject, the first question many Members and many in the listening audience might ask is, what is an isotope and why should we care about this? The reason is very simple. Isotopes are critical to millions of individuals and their families and to the Nation's health care system as a whole. Thousands of our citizens rely upon isotopes for diagnostic medical procedures each and every day, and annually up to 50,000 citizens rely upon them for therapy to treat illnesses such as thyroid disease.

These isotopes also support research and industrial activities that are essential to the Nation's competitiveness and economic health. Indeed, by DOE's own admission, isotopes provided by the Department "have touched the lives of virtually every citizen" in our country.

Yet despite the essential nature of isotopes to our health of our citizens and the economic well-being of our Nation, the Department of Energy told us in August 1992 that the program simply "wasn't a high priority." This position was so alarming and discouraging that Congressman Clinger and I immediately wrote then-Department of Energy Secretary Watkins about the critical need to reexamine this essential program and to resolve the problems that we are going to explore again today.

Unfortunately, our extensive review since then suggests that those problems have not been resolved and that our supply situation today is even more precarious than it was 15 months ago. For example, approximately 90 percent of all United States medical isotope requirements are now dependent upon a single isotope production reactor in Canada. In the event of a reactor outage or work stoppage at that Canadian facility, the United States has no backup capability. As a result of any shutdown there, we would face a virtual crisis in the health community within a matter of days.

Earlier this year, the medical community expressed concern that Congress should not ignore "the warning signs for complete breakdown of the radioisotope infrastructure" in the United States. I hope this followup hearing makes clear that we are not ignoring the problems facing this program and that we are not satisfied to allow the Department to ignore them either. In fact, this is precisely why we are here today, even though Congress is in recess.

Given the importance of isotopes for medical, research, and industrial activities, we are extremely concerned over the Department's lack of progress in coming to grips with the problems we examined in our last hearing. Facing up to these problems may have budgetary impacts on the Department. Because the administration is in the process of completing work on the fiscal year 1995 budget for those programs, I thought it would be unwise, very candidly, to wait until Congress returns in late January to schedule this hearing.

We are going to examine this matter in detail today. We are going to look at the Department, what the Department has done since that August 1992 hearing to resolve the problems facing the program, and we are going to look at what they have not done. We are going to ask them for certain assurances today from the highest levels of the Department, and for progress reports in the future so that we can know that commitments are being fulfilled by meaningful action.

I want to thank my colleague, Mr. English, who is not a member of the subcommittee, but a member of the full Committee on Government Operations, for joining us this morning; and I would call on him at this time for any opening statement.

Mr. ENGLISH. Well, I simply want to thank the chairman for his hospitality in asking me to join him; and it is a pleasure to be here once again, but I have no opening statement.

Mr. SYNAR. Thank you, Glenn.

Mr. Hastert will have an opening statement, and we will leave the record open for all opening statements from our colleagues.

At this time, I would like to call on our first panel this morning, Dr. Richard Hahn, Brookhaven National Laboratory; Roy W. Brown, Mallinckrodt Medical Inc.; Dr. Robert Atcher, University of Chicago Medical Center; and Dr. Iain Trevena, Nordion International. If they would all please come forward.

Gentlemen, in order not to prejudice past or future witnesses, it is the policy of this subcommittee to swear in all our witnesses. Do any of you have any objection to being sworn?

If not, if you would rise and raise your right hands.

[Witnesses sworn.]

Mr. SYNAR. Welcome, gentlemen, and we do appreciate your coming today, even though we are in recess. We will have Members coming in and out.

This subject is so important, as I said in my opening statement, that I thought it just couldn't wait until next year.

Dr. Hahn, why don't we begin with you? First of all, welcome back. You were with us in August 1992, and I would be very interested to hear your thoughts as we have proceeded over these last months.

Each one of your statements will be made part of the record, and we ask you all to summarize now in about 5 minutes apiece.

Dr. Hahn.

STATEMENT OF RICHARD L. HAHN, Ph.D., NUCLEAR SCIENTIST AND GROUP LEADER, CHEMISTRY DEPARTMENT, BROOKHAVEN NATIONAL LABORATORY, ON BEHALF OF THE NATIONAL ACADEMY OF SCIENCES

Dr. HAHN. Thank you, Mr. Chairman. I am very pleased to be back. As you may recall, when I was here in August 1992, I appeared as chairman of the committee of the National Academy of Sciences/National Research Council [NRC] that had been looking at this issue. It turned out that this past summer my 6 years on that NRC committee ended, but you were kind enough to ask me to come back to testify.

Just a few words of introduction: my whole career has essentially been spent at DOE national laboratories. I have been at Brookhaven the last 7 years. Before that, I spent about 24 years at Oak Ridge. I have been involved in the research area of nuclear chemistry and nuclear physics. I have used many isotopes; essentially my whole career has been built on using enriched and radioactive isotopes.

I am not involved in any way in isotope production, but I am familiar with many of the facilities at the different DOE labs and the people who work there.

Now for a little history: When I spoke to you in the summer of 1992, the NRC committee I chaired had, a few months before, held an informal workshop to look at the various problems that people in different scientific communities were finding with regard to isotope supply. Shortly before you held your hearing, the GAO issued its report; and then at the hearing itself, the DOE announced that the Arthur Andersen consulting company was going to evaluate their program. Andersen Co. issued its report recently. I will allude to that report briefly in a couple of my verbal comments.

To make the record clear, I am here essentially expressing my personal views in the sense that there have been no recent formal documents about isotopes written by the National Academy. Even our committee's 1992 workshop was an informal thing, organized to scope things out. So there is nothing formal that I can quote. On the other hand, the Academy's Institute of Medicine currently is doing a study that was, I believe, requested by the DOE to look mainly at the issue of the biomedical isotopes; a statement of the scope of that study is available.

Now, what about the current status of DOE's isotope production? So far as I could see in looking back at my written testimony from August 1992, things have not changed very much in the last 1½ years. Even with regard to the recommendations of the GAO report on how to improve the situation at the different isotope production centers in this country, it looks as if in most instances, conditions have continued to deteriorate just because nothing positive has been done.

The electromagnetic isotope separators, the calutrons, which are located at Oak Ridge, have long been the work horses of isotope enrichment because they can handle many of the different elements in the periodic table. Electromagnetic separation, in a sense, is a generic process.

The calutrons' program there is currently barely viable. Their existing inventory of isotopes, not only in what was called the traditional sales pool, but also in a select collection of isotopes reserved for research, is now being drawn down in order to meet current sales orders. The managers there have told me that they have been able to reduce their costs by cutting back to what they call a skeleton crew. But by the same token, many people who were trained in operating those facilities have been lost.

A very serious complication in the isotopes picture is the strong sales competition from the Russian isotope inventory. The report by the Andersen company states that the current worldwide market for stable isotopes is on the order of $8 to $10 million, and the Russians got into that market before the fall of the Soviet Union, even before they adopted some of the tenets of capitalism. They got into it aggressively, routinely undercutting published DOE prices by at least 10 percent.

At present, they are working very hard to sell as many isotopes as they can, and it looks as if they are willing to cut their prices to the bone, just to have the market.

In fact, just last Friday there was an article in the New York Times; I have brought a few copies with me, in case you are interested. The Times has been running a series on what is happening in Russia in terms of shifting over from a military dominated to a consumer-dominated economy. In this last article in the series, a laboratory outside of Moscow was mentioned that was run by the Russian Atomic Energy Ministry. The article describes Russian efforts there at what they call "conversion"; and it was mentioned specifically that they are exploiting a large Western market that uses radioactive isotopes for cancer diagnosis and treatment. So the Russians may be long-term players in this isotopes market.

More and more of my colleagues in the basic research community tell me that they are buying their isotopes, their enriched nonradioactive isotopes, from the Russians—mainly because of the lower prices. The quality of the product in general seems to be good. The reliability of the delivery also seems to be satisfactory. On the other hand, I have heard some stories of dissatisfied customers having problems, for example, that the isotope enrichment was not as advertised when they received the product.

I myself had an experience concerning United States and Russian isotope production in my work in an international scientific collaboration. We wanted to buy about 100 pounds of an enriched chromium isotope from the DOE gas centrifuge facility at Oak Ridge, and in dealing with the facility managers, even though they were trying to operate as a business, I found that they had essentially no freedom to negotiate. They had rather strict financial rules that they were bound by.

In fact, there was a for-profit company in Western Europe that was underbidding Oak Ridge, claiming that it could make a profit even at the lower price. In the end, my European colleagues, who raised the money for this particular aspect of the work, decided to go to the Russian gas centrifuges, and they got a price about half of what Oak Ridge was offering.

So during the time that the Russians were manufacturing the material for us, the gas centrifuges at Oak Ridge essentially were put into a standby mode.

At present, it looks as if the United States research community is getting the isotopes it needs, either from the existing United States inventories or from the Russian production, but there is much uncertainty concerning the Russian program. No one I have spoken to in the isotopes field in the United States can tell me the extent of the Russian inventories or what priorities they have in terms of future production. We don't know if they are just drawing down their inventory or if they are actually replenishing their supplies with new isotope production, so their reliability as a supplier for the long term is not clear.

I want to point out another aspect of uncertainty, namely that unless the situation changes in this country, if the Russians keep on underbidding the other isotope producers, it may well turn out that they become the prime producer, the prime supplier, in the worldwide market. I think there is a serious question to ponder, that is, has anyone really considered the long-term ramifications for science and technology in this country if we get to a stage where we have to go overseas to one supplier for all of the enriched materials we need?

At this point, I would like to say a few words about the importance of isotopes in research. There are about 230 isotopes that are listed in the DOE–IPDP inventory, but only a handful of these are what you might call big sellers in the commercial market, in the biomedical market; the rest are used primarily in research. These "research isotopes" are bought intermittently in relatively small amounts, tenths of a gram to a few grams at a time. So the perception exists that these isotopes are relatively unimportant financially.

Many members of the research community nationally are concerned that as more emphasis is put on the use of the small group of profitable isotopes in medicine and in industry—and certainly we realize the importance of those uses—all the other isotopes may fall by the wayside. I was thinking about the importance of isotopes in research and about how I could get across the idea of how a scientist would use these things, and I came up with an analogy. I am not sure how apt it is, but I will play it by you.

In a lot of ways, isotopes are the tools of the scientific trade, what you might call part of the "nuts and bolts" of doing the work; and I thought, what if there were a consumer who went to his favorite hardware store, expecting to find some of the nuts and bolts he needed for a job. How would he react if he were told that the price of an item suddenly had gone up by a factor of 5 or 10, or that the item was back-ordered with an indefinite delivery date, or perhaps worst of all, that it would no longer be manufactured?

In a similar way, a scientist really doesn't think too much about the supply of a particular isotope. He expects that he can pick up the phone, call the isotope sales office, and say "I need this much, how much is it and when can you ship it?" Now, if he needs an extraordinarily large amount, then he is prepared perhaps to negotiate or to wait. But for many isotopes he expects his purchase to be routine.

If instead he finds that the particular isotope he needs is not available, it is conceivable he can find a substitute and still carry out his research. But if he gets to the point where many isotopes have disappeared or if the prices have become unaffordable, then it is very likely that his particular research will have to be terminated. I know of a few real-life situations that have followed this scenario.

On top of this, in terms of trying to predict future isotope use, we must realize that research is very dependent on recent results. For example, I could perhaps predict what isotopes I might need 5 years from now, but it is very possible that 5 years from now I might have found that there was something more important to pursue than my original prediction.

Mr. SYNAR. Doctor, why don't you start to conclude?

Dr. HAHN. Yes, OK; two last points I want to make.

The first is that the radioactive isotopes that will be used in medicine also are used in research. In a lot of ways, the medical isotopes are the spinoff from research that was done earlier by physicists and chemists; and then people who were interested in the biological and medical applications realized their potential importance. So even in the field of nuclear medicine, it is not as if you pick an isotope today and tomorrow you can administer it to a patient. It takes years of research and development; in addition, one is always on the lookout for new products, so you need isotopes.

The very last comments I want to make have to do with what the Arthur Andersen report had to say in terms of production of these so-called financially unimportant research isotopes. They concluded that trying to produce these many different isotopes is not commercially viable; it is a venture that is bound to lose money. The Andersen report made the statement, that if you are going to try to justify production of research isotopes solely in business terms, you should essentially consider shutting the production down. However, if there are other reasons that are considered important to justify future production, then you should evaluate those reasons independent of business considerations. I would argue, because so much of the research in this country, which is funded by so many different Federal agencies, relies on these isotopes, that one could make an argument that it is in the national interest to guarantee the isotope supply here. In my opinion, this is an important issue that requires serious discussion and a definite policy decision at a high level of government.

[The prepared statement of Dr. Hahn follows:]

UPDATE ON THE SUPPLY OF ENRICHED ISOTOPES FOR RESEARCH

Statement of

Richard L. Hahn, Ph. D.

Former Chairman of the Committee on Nuclear and Radiochemistry
of the National Research Council
and
Nuclear Scientist and Group Leader
Chemistry Department
Brookhaven National Laboratory

before the
Subcommittee on Energy, Environment, and Natural Resources
Committee on Government Operations
U.S. House of Representatives

December 6, 1993

I. INTRODUCTION.

Good morning, Mr. Chairman and members of the Subcommittee. I am Dr. Richard L. Hahn. I am pleased to have been invited back to talk with you to follow up on my testimony about isotopes that was presented at your August 12, 1992, hearing. At that time, I appeared before you as Chairman of the Committee on Nuclear and Radiochemistry of the National Research Council (NRC). My six-year tenure on that NRC Committee ended in July of this year. As you know, the NRC is the operating arm of the National Academies of Science and Engineering.

Professionally, I am a tenured scientist in the Chemistry Department at Brookhaven National Laboratory, where I am the leader of a research group that is part of a large international collaboration that is studying solar energy production by observing subnuclear particles called neutrinos that are emitted from the sun. I think it is noteworthy in the context of today's hearing that several stable enriched isotopes play important roles in this research project, even though its major import is in the fields of astrophysics and elementary particle physics.

I have been at Brookhaven since 1987; the funding for my group's research comes from DOE's Office of Energy Research. Before that I spent 24 years as a research scientist at the Oak Ridge National Laboratory with funding from the AEC, ERDA and DOE. Essentially all of my scientific career has been in the fields of nuclear chemistry and physics, mainly involving research with enriched stable and radioactive isotopes; in fact, I am a co-discoverer of more than twenty radioactive isotopes. As you are aware, both the Brookhaven and Oak Ridge National Laboratories have major facilities that are part of the DOE Isotope Production Program. I am not involved in isotope production but I am familiar with these facilities and their scientific personnel, as well as those at other DOE-supported installations.

II. SOME BRIEF HISTORY

When I spoke to you some sixteen months ago, our NRC Committee had recently held an informal workshop exploring concerns in the different isotope-user communities about supply and future availability of these special materials. The GAO had issued its report on the problems in the DOE isotope programs. At your August 1992 hearing, the DOE Office of Nuclear Energy announced that it had retained the services of a consultant, the Arthur Andersen Co., to evaluate and make recommendations about the isotope production programs. The consultant's report was issued earlier this year; I will refer to it a few times in my comments that follow.

Reading my written testimony given at your hearing last year, I find that most of what I said then is still valid today, especially with regard to enriched stable isotopes used in basic research. At this point, I want to emphasize that my remarks today, as in August 1992, do not represent any official position of the National Research Council or National Academy of Sciences. Our Committee work in 1992 was informal, with the intent of identifying issues pertinent to isotope production that were deserving of in-depth study. Currently, the NAS Institute of Medicine is conducting a study of isotopes of biomedical interest, but that group's work is not finished. Thus, no recent formal NRC/NAS report on these topics exists that I can quote. My comments are based on my perceptions as well as on discussions I have had in the past few weeks with several colleagues who either participated in our committee's workshop and have maintained their professional interest in the problems of isotope availability, or are directly involved in the isotope production program.

III. CURRENT STATUS OF ISOTOPE PRODUCTION IN THE U.S. AND IN RUSSIA

For the most part, I will limit my remarks to the production of enriched stable isotopes. I believe that other panelists today will address issues relevant to the production of radioactive isotopes.

So far as I can ascertain, little if anything has been done since the GAO Report to improve the situations at the U.S. DOE isotope enrichment centers. Instead, conditions have continued to deteriorate.

The electromagnetic isotope separators (the Calutrons) at Oak Ridge, which have long been the work horses in the isotope enrichment field because they can handle most of the chemical elements that exist, have been shut down in a standby mode since August 1991. The program there is barely viable. The existing inventory of enriched isotopes, not only from the traditional sales pool but also from the research materials collection (which had been previously reserved for loans), is being depleted to meet current sales orders. The managers of the Calutrons have been able to reduce their costs by cutting back to what they call a skeleton crew. But this approach has served to exacerbate an already bad situation, namely that trained personnel there are being lost, either transferred to new responsibilities or retired from the program.

A serious complication in the Calutron story is due to strong sales competition from Russian isotope inventories (The report by Arthur Andersen Co. sets the current world-wide market for stable isotopes at 8 to 10 million dollars). Since the 1940's, a strong enrichment program was built up in Russia, just as was done in this country, using electromagnetic separators and gas centrifuges. In recent years, even before the downfall of the Soviet Union, the Russian isotope producers entered the isotope sales market aggressively, routinely undercutting the published DOE prices by at least 10%. In their present quest for hard currency, the Russians seem to be willing to set their prices at ridiculously low levels to ensure the sale of their products.

More and more of my scientific colleagues in the basic research community are telling me that they are buying their enriched isotopes from Russia, mainly because of the lower prices compared to what DOE has to offer. Quality of the Russian products and reliability of delivery seem in general to be satisfactory, although I have heard some stories from dissatisfied customers, who complained that in some particular instances, the level of isotopic enrichment was less than advertised, or the product was not chemically pure.

In my own experience, as part of my solar neutrino research, I was involved over the past few years in exploring the possible enrichment of many kilograms of a chromium isotope at gas centrifuges. I found that the Oak Ridge DOE centrifuge facilities had essentially no freedom to negotiate a price and, as a result, had difficulty in matching even the bid of a West European for-profit company; and the Oak Ridge price was more than twice as expensive as the low bid received from the Russian Kurchatov Institute. My European colleagues in our collaboration, who raised the money for this material, naturally chose the Russians to do this special job. The quality of the material produced and shipped to us during the past year has met our specifications and there have been only minor delays in the delivery schedule. During the same period that the Russians were doing this work, the Oak Ridge centrifuges were put into a standby mode and many of their staff members were transferred to other projects.

It appears that at present the U.S. research community is getting the isotopes it needs, either from existing U.S. inventories or from Russian production. However, there is much uncertainty concerning the Russian program. No one that I have spoken to in the isotopes field knows the extent of the Russian inventories, or what priorities have been set in their isotope production plans. Are their inventories being depleted, as they are in the U.S., or are they being replenished in new production runs? How reliable will the supply of particular isotopes be in the future? I might speculate that to gain a high immediate return on their investment, the Russians will concentrate their efforts on the big sellers, the few isotopes routinely being used in medicine and industry, at the expense of the many different isotopes that are used in research. Some data presented in the Andersen report seem to support this scenario.

In addition to this element of uncertainty of future Russian supplies, there is a separate issue that I think should be considered, namely that, unless the situation changes in this country, the Russians may be able to corner the enriched isotopes market. Has anyone considered the desirability of possible future effects on U.S. science and technology if only one isotopes producer, located overseas, were able to dominate the market?

There is one bright note to report about the Oak Ridge Calutrons. A long-term contract was recently signed with Amersham Co. for enrichment of a particular isotope that is to be incorporated into a drug for human consumption. Because of the requirement of USFDA approval of this material, Oak Ridge was the obvious choice as supplier, as compared to the Russian producers. It's possible that because of this contract, the Calutrons may be restarted in 1994 on a part-time basis, to provide this and a few other selected isotopes of commercial interest.

Finally, I note that when our NRC Committee ran its workshop two years ago, serious concerns were raised about supplies of the so-called "life-science" stable isotopes, such as ^{18}O, ^{13}C, and ^{15}N. I have learned that this situation has certainly improved since then, with reliable production provided by two for-profit companies.

IV. THE IMPORTANCE OF ISOTOPES FOR RESEARCH

DOE has more than 230 stable separated isotopes in its IPDP inventory. Of these, only a handful are big sellers in the world market, with the majority being used in medical applications. The rest are used primarily in research, and as such, are bought intermittently in relatively small amounts, from fractions of a gram to a few grams at a time. Thus the perception exists that the research isotopes are relatively unimportant financially, even though the Andersen Report lists a worldwide market for these isotopes of more than three million dollars.

If you couple these perceived market forces with the fact that it is far easier to explain to a non-specialist the need for a particular isotope in a medical procedure compared to its use in a research project in physics or chemistry, you can see why many members of the research community are concerned that the research isotopes are in danger of being ignored or forgotten in this debate over isotope supply.

However, from the perspective of many of the scientists who participated in our NRC workshop in 1992, who are users of these isotopes, the importance of these research isotopes cannot be over-emphasized. In many areas of research, these isotopes are some of the "tools of the trade", the "nuts and bolts" without which the work cannot be done. Consider the analogy of a consumer who goes to a reliable hardware store, expecting to find the nuts and bolts that he/she needs for some job at home. What will that customer do if told that the price of the required items was recently increased five or ten-fold, or that the items are back-ordered with an indefinite delivery date, or worst of all, are no longer available? In a similar manner, a scientist will contact the isotopes sales office, expecting that the particular isotope needed for his/her current research project is sitting on the shelf, available at an affordable price. If that isotope is not available in the amount required, it's possible that some substitute can be found that will do the job. But if too many isotopes have disappeared from the inventory, or if the prices have become "unaffordable", it's likely that a promising research direction will have to abandoned.

Complicating this situation is the fact that research plans often must change as new results are obtained, so that it's usually difficult to predict today what particular isotope(s) will be crucial to my research in a year or two. The bottom line of this discussion is that a wide inventory of isotopes must be available if scientific research is not to suffer.

I know of several real-life cases where promising research work was terminated because of lack of the needed isotopes or steep price increases. In fact, I was told of one instance, where a well-known company in the nuclear medical field had done promising R&D on a new radioactive agent using small amounts of a particular isotope, but was prevented from proceeding to the next phase of their work because the larger amounts that were required did not exist.

V. A RESEARCH CONTINUUM FROM PHYSICAL SCIENCE TO BIOMEDICINE

My remarks above tended to focus on research in the physical sciences. At this point, I want to shift gears and remind you that the properties of most (if not all) of the radioactive isotopes that are commonly used in medicine today were discovered by nuclear physicists and chemists. The motivation of that work was - and still is - the desire to gain an understanding of the basic rules of how nuclei are put together ("nuclear structure"), how they decay and how they relate to neighboring isotopes. The utilization of these isotopes in medicine was a significant spinoff of this earlier research, when it was realized that the known radiations emitted by some radioactive isotopes (and possibly their chemical behavior) made them suitable for diagnostic or therapeutic treatments.

Research with enriched and radioactive isotopes is an important component of biomedical science. The National Biomedical Tracer Facility, which you will hear a lot about today, is intended by its proponents to be a dedicated facility for biomedical research, not a commercial producer of isotopes. The process of going from the idea of a possible medical isotope to the development of a potentially usable nuclear medical product that can be tested in clinical trials can itself take several years. Success is not assured in these endeavors. More potential therapeutic or diagnostic agents end up on the cutting room floor than in the physician's treatment bag. To increase the chances of success in this research, a large variety of enriched stable isotopes will be required as targets at the NBTF.

VI. THE BOTTOM LINE?

I want to conclude my remarks by noting that I found the Report by the Arthur Anderson Co. to be an incisive study of the DOE Isotopes Production Program. In particular, I found two statements about the production of the research isotopes to be especially thought provoking, and relevant to the points I have tried to make.

Instead of quoting the Report directly, I will paraphrase these points:

1. The production of the relatively small amounts of many different separated isotopes is not a commercially viable operation. It is bound to lose money.

2. Since this production cannot be justified in terms of business decisions, it was recommended that the government must decide if other reasons exist to justify future production of these materials. If so, this production should be subsidized; if not, it should be terminated.

It seems to me, that the fact that many federal agencies, not only DOE, but NSF, NIH, EPA, and FDA to name a few others, support a wide variety of scientific research programs is proof that such research is considered to be "in the national interest". I would then argue that, since some fraction of this research requires supplies of enriched and/or radioactive isotopes, a clear reason exists for the government to fund at least part of the isotope production program.

Perhaps not everyone will agree with my conclusion. At the minimum, I think that a discussion of the issues raised in points 1 and 2 above is called for, possibly resulting in a policy decision about the fate of enrichment facilities in the United States.

Mr. SYNAR. Dr. Atcher.

STATEMENT OF ROBERT W. ATCHER, Ph.D., INVESTIGATOR, UNIVERSITY OF CHICAGO MEDICAL CENTER, CHICAGO, IL, ON BEHALF OF THE SOCIETY OF NUCLEAR MEDICINE AND THE AMERICAN COLLEGE OF NUCLEAR PHYSICIANS

Dr. ATCHER. Thank you. The Society of Nuclear Medicine and the American College of Nuclear Physicians are pleased to offer the following testimony regarding the Department of Energy's Isotope Production and Distribution Program.

The Society's membership of over 14,000 represents physicians, physicists, chemists, radiopharmacists, technologists, and others interested in diagnostic, therapeutic, and investigational nuclear medicine applications. The College is comprised of approximately 1,500 certified physicians, scientists, and corporations engaged in the practice of nuclear medicine.

My name is Robert Atcher. I am the immediate past president of the Radiopharmaceutical Science Council of the Society of Nuclear Medicine, a group who uses isotopes in all forms daily. I am an investigator at the University of Chicago, who works with radionuclides in the clinic and in the lab. I was responsible for the DOE isotope production program at Argonne National Laboratory until fiscal problems forced us to mothball that effort. I was also director of the Nuclear Medicine Research Program at Argonne. In short, I am involved in every facet of isotope production.

My father always repeated a simple adage. Be careful what you wish for, because you might get it. DOE wished to centralize isotope production under one office. Thus, the isotope production and distribution office was born. It became apparent, however, that three major problems faced this program.

First, the revolving fund was profoundly undercapitalized from the beginning. Second, strategic planning was necessary for this program to be effective. In fact, the program has been consumed by crisis management. Third, since many of the facilities were operated for and by other DOE programs, decreasing budgets led to decreased operating schedules for isotope production, which necessarily meant decreasing revenues flowing back to the revolving fund. In short, the program was caught in a crunch for money, time, and adequate facilities.

When the IPP was established, full cost recovery was mandated. It must be emphasized that, ironically, every other first world nation utilizes government-subsidized facilities for isotope production. For those in research, the IPP meant that it became necessary to rob Peter to pay Paul. Investigators, all of whom have fixed budgets for their research programs, were faced with dramatically escalating costs for isotopes, as Dr. Hahn indicated. In reality, fewer experiments and patients could be studied, extending the time and cost required to develop new compounds.

Federally funded investigators found it necessary to pay full cost recovery to purchase research isotopes from a Federal program. We experienced this at the University of Chicago for projects which we had proposed for the treatment of gynecologic cancers.

In examining the status of the DOE Isotope Production and Distribution Program, it is fair to say that no part is working well.

The program is composed of three major components. One is enriched stable isotopes. They are used to examine fundamental scientific problems in physics, chemistry, biology, nutrition, agricultural, and environmental research. They are also used as targets in reactors and accelerators to produce radioisotopes for research and the clinic. This part of the program has ceased entirely.

The second component is reactor-produced isotopes. The workhorse of nuclear medicine imaging, technetium-99m, is produced in a reactor. In addition, reactors produce isotopes that have great promise in the treatment of disease, particularly cancer. There is no domestic source of technetium-99m, and the other reactor operations are struggling.

The third component of isotope production is accelerator-produced radionuclides. Members of our community recognized that providing accelerator-produced radionuclides as a parasitic operation at high energy physics facilities was doomed by decreasing operating budgets and shorter schedules at these facilities.

The Society of Nuclear Medicine and the American College of Nuclear Physicians received a grant from DOE to examine this problem. This study and two other reports concluded that a dedicated facility constructed to produce radioisotopes for research, to perform R&D on radioisotope production and radiopharmaceutical synthesis, to educate, to train and, lastly, and the lowest priority, to produce isotopes for commercial use was necessary.

In response to this report and the direction of Congress, the Department of Energy recently released a request for proposals to begin the development of an accelerator called the National Biomedical Tracer Facility. The constraints included in the criteria for selection, particularly the demand that this facility be operated in what amounts to full cost recovery for its operation and construction costs, are simply unworkable. If this requirement is mandated by Federal law, then the law must be changed to reflect the reality of the situation.

When radionuclides developed by the R&D program at the NBTF become commercially viable, then, as has repeatedly happened historically in the DOE-sponsored nuclear medicine program, the technology will be transferred to industry and the marketplace will bear the costs of production. No other DOE facility in the Nation is constrained to recover the cost of its activities in research and development, education and training by the sale of its services, not to mention the cost of its construction.

Paradoxically, nuclear medicine, a sterling success story in technology transfer before anyone had ever heard of the term, has been made a victim of its own success.

In summary, we ignored a piece of wisdom well known to Members of this body: If it ain't broke, don't fix it. To many observers, the DOE activity in isotope production was never broken, but we tried to fix it anyway, and we failed miserably.

We must reexamine the issue and create an isotope production system that works. I am here to assure you that the Society of Nuclear Medicine and the American College of Nuclear Physicians are ready to assist DOE and the Congress in putting isotope production back on track. The benefits to the citizens of this country will be immediate.

Thank you.

Mr. SYNAR. Thank you.

[The prepared statement of Dr. Atcher follows:]

ACNP
American
College of
Nuclear
Physicians

1101 Connecticut Avenue, N.W. • Suite 700 • Washington, D.C. 20036
(202) 429-5120 Fax (202) 223-4579

SNM
The Society
of Nuclear
Medicine

STATEMENT BEFORE

U.S. HOUSE OF REPRESENTATIVES

ENVIRONMENT, ENERGY, AND NATURAL RESOURCES SUBCOMMITTEE

GOVERNMENT OPERATIONS COMMITTEE

U.S. DEPENDENCE ON FOREIGN ISOTOPES

Presented by

Robert W. Atcher, Ph.D.

Representing the

Society of Nuclear Medicine

and

The American College of Nuclear Physicians

December 6, 1993

For more information, contact:
David C. Nichols, Legislative Coordinator
Phone: (202) 429-5120

Oral Testimony
House Government Operations Committee
Environment, Energy, and Natural Resource Committee
December 6, 1993

The American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM) are pleased to offer the following testimony regarding the Department of Energy's Isotope Production and Distribution program. The Society's membership of over 14,000 represents physicians, physicists, chemists, radiopharmacists, technologists, and others interested in diagnostic, therapeutic, and investigational Nuclear Medicine applications. The College is comprised of approximately 1,500 certified physicians, scientists, and corporations engaged in the practice of Nuclear Medicine.

My name is Robert Atcher. I am the immediate past president of the Radiopharmaceutical Science Council of the Society of Nuclear Medicine representing those charged with the formulation of the compounds used routinely in clinical Nuclear Medicine practice and the researchers who develop those new compounds. I am an investigator at the University of Chicago who is actively working on both routine clinical matters and the investigation of new agents. I was responsible for the DOE isotope production program at Argonne National Laboratory until the fiscal problems forced us to mothball that effort . I was also director of the Nuclear Medicine Research Program at Argonne. So I am involved in every facet of isotope production.

In examining this issue, two pieces of wisdom keep coming back to me. The first is the simple adage: Be careful what you wish for because you might get it . Many who were involved in isotope production at DOE believed that putting those efforts under the direction of a single office would be the best way to operate . Thus, the Isotope Production and Distribution Office was born . It became apparent, however, that three major problems faced this program . First, the revolving fund was seriously undercapitalized from the beginning . The second was that strategic planning was necessary for this program to be effective . Instead, the program was consumed by crisis management . Third, since many of the facilities were operated for and by other DOE programs, decreasing budgets lead to decreased operating schedules for the facilities which in turn meant decreasing revenues flowing back to the revolving fund . In short, the program was caught in a crunch for time, money, and adequate facilities.

When the Isotope Production Program was established, the presumption was that full cost recovery could be achieved from the sale of isotopes . It must be emphasized that, ironically, every other first world nation utilizes government subsidized facilities for isotope production . For those in research, it became necessary to rob Peter to pay Paul . Investigators, all of whom had fixed budgets for their research programs, were faced with dramatically escalating costs for isotopes . In reality, fewer experiments and patients could be studied, extending the time and cost required to complete the preliminary investigations of these promising new compounds for diagnosis and therapy . In essence, federally funded investigators found it necessary to pay full cost recovery to purchase isotopes from a federal program . We experienced this at the University of Chicago for projects which we had proposed for the treatment of gynecologic cancers.

In examining the status of the DOE Isotope Production and Distribution Program, it is fair to say that no part is working well . The Isotope Production Program is composed of three major components . One is enriched stable isotopes . They are used to examine fundamental scientific problems in physics, chemistry, biology, nutrition, agricultural and environmental research . They are also used as targets in reactors and accelerators to produce radioisotopes for research and the clinic . This function has ceased.

The second component is reactor produced isotopes . The workhorse of Nuclear Medicine imaging, Technetium-99m, is produced in a reactor . In addition, reactors produce isotopes that have great promise in the treatment of disease, particularly cancer . This function is struggling.

The third component of isotope production is accelerator-produced radionuclides . These isotopes make up a critical part of the clinical and research Nuclear Medicine Practice . Members of our community recognized that providing accelerator-produced radionuclides as a parasitic operation at high energy physics facilities was doomed by decreasing operating budgets and shorter schedules at these facilities . The Society of Nuclear Medicine and the American College of Nuclear Physicians received a grant from DOE to examine this problem . This study and two other reports concluded that a dedicated facility, constructed to produce radioisotopes for research, to perform R&D on radioisotope production and radiopharmaceutical synthesis, to educate, to train, and, lastly, to produce isotopes for commercial use was the most acute need among the three components of isotope production .

The Dept. of Energy recently released a Request For Proposals to begin the development of the National Biomedical Tracer Facility . The constraints included in the criteria for selection, particularly the demand that this facility be operated in what amounts to full cost recovery for its operation and construction, are simply unworkable . If this requirement is mandated by Federal law, then the law must be changed to reflect the reality of the situation . When these isotopes developed by the R&D program at the NBTF become commercially viable then, as has repeatedly happened historically in the DOE sponsored Nuclear Medicine program, the technology will be transferred to industry and the marketplace will bear the costs of production . No other DOE facility in the nation is constrained to recover the cost of its activities in research and development, education, and training by the sale of its services, not to mention the cost of constructing those facilities . Ironically, Nuclear Medicine--a sterling success story in technology transfer before anyone had ever heard the term--has been made a victim of its own success.

In summary, the second piece of wisdom that I recalled is well known to members of this body . If it ain't broke, don't fix it . To many observers, the DOE activity in Isotope Production was never broken . But, we tried to fix it anyway and failed miserably . So, it is time to re-examine the problems and create an isotope production system that works . I am here to assure you that the Society of Nuclear Medicine and the American College of Nuclear Physicians are ready to assist DOE and the Congress in putting this essential activity back on track . The results are not intangible gains in human wisdom--they are improvements in the health and well-being of the citizens of this country.

Thank you for allowing me to testify before you today, at this time I will be happy to answer any questions you may have.

Written Testimony

I. INTRODUCTION

The American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM) are pleased to offer the following testimony regarding the Department of Energy's Isotope Production and Distribution program. The SNM's membership of over 14,000 represents physicians, physicists, chemists, radiopharmacists, technologists, and others interested in diagnostic, therapeutic, and investigational Nuclear Medicine applications. The ACNP is comprised of approximately 1,500 certified physicians, scientists, and corporations engaged in the practice of Nuclear Medicine.

My name is Robert Atcher. I am appearing here today because I represent the focus of many of the issues which are being discussed at these hearings. I am the immediate past president of the Radiopharmaceutical Science Council of the Society of Nuclear Medicine. representing those charged with the formulation of the compounds used routinely in clinical Nuclear Medicine practice. The Council also includes the researchers who develop the new compounds that will be used for diagnosis and treatment of disease in the 21st century. I am one of them--an investigator at the University of Chicago, who is actively working on new radiopharmaceuticals. I was responsible for the isotope production program at Argonne National Laboratory until the fiscal problems which will be detailed by others at this hearing forced us to mothball that effort. I was also director of the Nuclear Medicine Research Program at Argonne. I was directly involved in isotope production as a user for research and clinical practice, as a producer, and as an advisor.

Nuclear Medicine uses radioactive isotopes (radioisotopes or radionuclides) for several purposes: 1) diagnostic imaging, 2) measurement of physiologic parameters, 3) monitoring of disease and 4) treatment of disease. Through Nuclear Medicine, physicians can identify heart disease, cancer, complications of AIDS, epilepsy, infections, lung disease, or treat patients with hyperthyroid disease, like former President Bush and Mrs. Bush. Over 36,000 diagnostic Nuclear Medicine procedures are conducted each day in the United States. Approximately 50,000 therapies, and nearly 100 million laboratory tests are performed each year in U.S. Nuclear Medicine laboratories. Modern medicine is completely dependent on radioisotopes from research and development for clinical application.

Historically, patients around the world have benefited immensely from radioisotopes available through federal government programs, In the United States radioactive isotopes were produced by the Atomic Energy Commission (AEC); currently, those programs are operated by the Department of Energy (DOE). The DOE's mission within the Office of Health and Environmental Research (OHER), was to support Nuclear Medicine research. DOE's woeful response to this mandate was outlined in the General Accounting Office (GAO) report highlighted at a hearing before Representative Synar's Environment, Energy, and Natural Resources Subcommittee of the

House Government Operations Committee on Aug. 12, 1992[1]. If the U.S is to continue to excel in radioisotope based research, clinical radioisotope applications, and radiopharmaceutical manufacturing, it is essential that this country provide the support and infrastructure to maintain domestic capabilities for production of accelerator and reactor produced radionuclides and for enriched stable isotopes.

Examples of the supply problem are given in the following cases:

Case 1:

Copper-67 is a radioactive form of the metal. Studies using monoclonal antibodies labeled with ^{67}Cu have shown great promise in the treatment of a variety of cancers. Researchers at the University of California, Davis have funding from the National Institutes of Health (NIH) and DOE to study the utility of ^{67}Cu and have been limited to treating only a handful of patients. Because this isotope is not produced reliably, their work on lymphomas and other cancers has been severely limited.

Case 2:

Positron Emission Tomography (PET) is a technology that serves as a gold standard in Nuclear Medicine. It is so specific that it can pinpoint the focus of a seizure in epileptic patients, critical information to neurosurgeons operating on children. Without germanium-68 to calibrate PET scanners, the accuracy of these studies will be compromised.

Case 3:

A San Diego based biomedical company relies on radioactive gadolinium to determine the biodistribution and kinetics of experimental contrast agents for Magnetic Resonance Imaging (MRI). The company has been forced to use Gd-153, which has a half-life. of 241 days, throughout their clinical trials. Due to its long half life, this isotope generates low-level radioactive waste (LLRW) -- unnecessarily. A short lived version of gadolinium could be equally effective. If Gd-147, which has a 38 hour half life were to be available, this company would not have to generate LLRW. This committee is well aware of the controversy surrounding radioactive waste.

Case 4:

Another extremely promising cancer therapy would rely on astatine-211. Studies at Duke University and Argonne National Laboratory show that Astatine-211 is surprisingly effective in treating extremely aggressive cancers, such as neoplastic meningiomas and gynecological cancers like ovarian or breast cancer. Duke has equipment to produce limited quantities of this valuable isotope, but it is unable to support clinical trials in human cancer patients. The facility at Argonne to produce this isotope was shutdown due to lack of funds. A limited amount is also available for research from Duke. That facility is unable to produce the quantities needed for multi-center clinical trials.

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[1] "Nuclear Science: DOE's Self-Supporting Isotope Program Is Experiencing Problems", June 1992; GAO RCED 92 122FS

In examining this issue, two pieces of wisdom keep coming back to me. The first is the simple adage: Be careful what you wish for because you might get it. Many who were involved in isotope production at DOE believed that putting those efforts under the direction of a single office would be the best way to operate. Thus, the Isotope Production and Distribution Office was born. It became apparent, however, that three major problems faced this program. First, the revolving fund was seriously undercapitalized from the beginning. This fund was insufficient to handle the operational component of the program. When also used for capital improvements it accelerated the depletion. The second was that strategic planning was necessary for this program to be effective. Unfortunately, the program was consumed by crisis management. Many of these crises revolved around bringing the DOE laboratory system overnight into compliance with all of the mandated environmental, safety, and health regulations. This activity created shutdowns at production facilities without timelines for the resumption of activities. Many of these facilities were old and the upgrades were prohibitively expensive. Third, since many of the facilities were operated for and by other DOE programs, decreasing budgets lead to decreased operating schedules for the facilities which in turn meant decreasing revenues flowing back to the revolving fund. In short, the program was caught in a crunch for time, money, and adequate facilities. It appears in hindsight that a self sustaining isotope production program was overly ambitious. It must be emphasized that, ironically, every other first world nation utilizes government subsidized facilities for isotope production.

II. RESEARCH

The DOE research program in the use of radionuclides has been a paradigm for technology transfer. Once the material's commercial value was discovered, industry produced and distributed the product commercially. The total effect has been billions of dollars in domestic revenue. In fact, the radioisotope research and production program, per dollar invested, is a premier example of technology transfer from government for the direct benefit (including the medical applications and creation of jobs) of the citizens of the U.S. For example, DOE sponsored research led to the discovery of the 1) ^{99}Mo/^{99m}Tc generator, which is currently the only source of ^{99m}Tc for clinical radiopharmaceuticals in the United States and the rest of the world, 2) the Anger Camera, which is utilized in the majority of imaging studies in Nuclear Medicine, 3) ^{201}TI, which is used to image the majority of patients with cardiovascular disease and 4) F-18 Fluorodeoxyglucose (FDG), the mainstay for PET procedures, which was also developed with DOE sponsored research. This track record will cease if isotope supply is allowed to continue at the trickle existing today.

For the United States to retain its prominent role in the application of radioactive materials in medicine, it is essential that this nation provide a reliable, domestic source and supply of radionuclides. Despite our pioneering leadership in this field, we will soon rely on sources outside the United States for all of the isotopes necessary for research applications and clinical practice. The reactor and accelerator facilities that produce radionuclides for Nuclear Medicine, both domestically and abroad, are facing severe problems that adversely affect the supply of radioisotopes for health care. We cannot depend on foreign suppliers to provide the wealth of isotopes at a reasonable cost to support the vast array of research and clinical studies being performed in the U.S.

The lack of a continuous supply of accelerator-produced radionuclides poses a critical problem for Nuclear Medicine patients. Twenty years of DOE-sponsored research at Los Alamos National Laboratory (LANL) and Brookhaven National Laboratory (BNL) has shown that large DOE accelerators (at higher energies and higher beam currents than available with commercial accelerators) provided a number of unique radioisotopes for medical uses and clinical studies being performed in the U.S.

Accelerator-based radioisotope programs at LANL and BNL depend on the parasitic use of physics research accelerators. Declining budgets in these physics research programs have severely restricted the operating time of these accelerators and, as a result, curtailed the supply of radioisotopes needed by medical patients. The accelerator at LANL is scheduled for shutdown in FY 1995 at the latest. This will leave only BNL to produce radionuclides by high energy charged particles. An upgrade of the BNL accelerator, known as the Brookhaven Linac Isotope Producer (BLIP), is planned. It will marginally improve the supply of these radioisotopes. This upgrade is an interim solution since the BLIP and the associated isotope processing facilities are old and the production capabilities are limited. If the U.S. is to maintain a sufficient and reliable supply of accelerator isotopes, the National Biomedical Tracer Facility (NBTF) must be funded and operational as soon as possible.

In addition to the lack of high energy, high current particle accelerators in the U.S. for production of research and unique commercial radionuclides, support for routine operations has evaporated. The "revolving fund", operated by the Isotope Production and Distribution Program (IPDP) within DOE, as mandated by the Public Law 101.101, is bankrupt. The Management Study of the U.S. DOE IPDP by Arthur Andersen & Company[2], summarized the difficulties in maintaining a functional radioisotope production program based solely on complete cost recovery. The net result of this mandated program was to increase costs of the unique isotopes beyond the ability of U.S. researchers to pay, causing a severe drop in radioisotope orders. This, in turn, has led to a severe reduction in the development of new diagnostic and therapeutic radiopharmaceuticals in this country. This has restricted, and eliminated in many cases, the ability of U.S. companies to offer more sophisticated radiopharmaceuticals that physicians can use to diagnose and treat disease, particularly cancers, in a cost effective manner.

The lack of a domestic source of radionuclides produced either by high energy accelerators or reactors could not have come at a more inopportune time. Many new, highly specific biomolecules such as monoclonal antibodies, receptor binding agents or other compounds that can selectively target cells are being developed at a rapid pace. When coupled to radionuclides, these molecules will be powerful agents for diagnosis and therapy. Unfortunately, the very limited availability and high costs of useful radionuclides exclude most U.S. scientists in corporations, academia, or government laboratories from developing effective radiotherapeutic agents for treatment and possible cure of a number of cancers. For example, a recently developed receptor ligand (111In-octreotide) exhibits strong binding affinity to a variety of cancers exhibiting somatostatin receptors. It is being used to visualize the location of cancer sites in the body using SPECT imaging instrumentation, which is available in most Nuclear Medicine Departments in the U.S. This agent demonstrates that new radiopharmaceuticals based on specific receptor molecules will produce major improvements in our ability to diagnose and treat disease. If the U.S. is to participate in the development and marketing of these types of drugs, it is essential that the U.S. improve and maintain its commitment to make available the important radionuclides at a reasonable cost.

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[2] Arthur Anderson Report, February, 1993.

When the Isotope Production Program was established, the presumption was that full cost recovery could be achieved from the sale of isotopes. For those isotopes that were in commercial use, this was a hardship, but not an obstacle. For those in research, it became necessary to rob Peter to pay Paul. Investigators, all of whom had fixed budgets for their research programs from DOE or NIH, were faced with dramatically escalating costs for isotopes. One choice was to find other mechanisms to pay for these studies. In reality it meant that fewer experiments and patients could be studied, extending the time required to complete the preliminary investigations of these promising new compounds for diagnosis and therapy. In essence, federally funded investigators found it necessary to pay full cost recovery to do peer reviewed, federally funded research. We experienced this at the University of Chicago for projects which we had proposed for the treatment of gynecologic cancers. The cost of carrying out this research is also further complicated by the full cost recovery effort. This process results in a dramatic alteration in the cost of research isotopes from year to year.

III. NATIONAL BIOMEDICAL TRACER FACILITY (NBTF)

The first component of isotope production is accelerator-produced radionuclides. Members of our community recognized that providing accelerator-produced radionuclides as a parasitic operation at high energy physics facilities, was doomed by decreasing operating budgets and shorter schedules at these facilities. Two workshops produced position papers on the problem. The Society of Nuclear Medicine and the American College of Nuclear Physicians received a grant from DOE to examine this problem. This task force produced a report which was given to the DOE and communicated to Congress. All three reports agreed that a dedicated facility, constructed to produce radioisotopes for research, to perform R&D on radioisotope production and radiopharmaceutical synthesis, to educate, to train, and, lastly, to produce isotopes for commercial use was the most acute problem of those faced by the three components of isotope production. The isotopes that this National Biomedical Tracer Facility will produce coupled with some of the exciting new developments in molecular biology, provides opportunities to make a quantum leap in our ability to diagnose and treat disease. At the University of Chicago, we are anticipating using some of these isotopes for the diagnosis and treatment of breast cancer, gynecological cancers and prostate cancer, to name a few.

In 1991, the Society and College, in cooperation with the DOE, presented to Congress a feasibility study of a National Biomedical Tracer Facility (NBTF). The study concluded that the U.S. urgently needs an NBTF to produce radioisotopes for Nuclear Medicine research and clinical practice. Furthermore, this national resource, due to its research and educational components, would enable America to compete in the rapidly developing fields of radiologic and biomedical science. The NBTF would also provide radioisotopes for scientists working in many other fields, such as nutrition, genetics, molecular biology, pharmacology, drug development, nuclear physics, environmental research, geology, and industrial manufacturing. It would also permit us to lead the world in the development of radionuclide synthesis with minimal radioactive waste production.

In 1989, two additional DOE documents,[3,4] similarly proposed that the DOE establish an accelerator facility dedicated to the continuous production of radioisotopes for biomedical applications. Despite these studies, DOE has contracted for yet another study with the National Academy of Science - Institute of Medicine, delaying the process even further.

The NBTF proposal was developed with input from industry, academia, and government. The Society obtained a grant from the DOE to explore and resolve the problems of isotope availability. The grant was funded in response to the FY 1991 Energy and Water Appropriations Subcommittee Manager's Report, which directed the Secretary of DOE to report on the need for an NBTF. The study was transmitted to Congress by former DOE Secretary Watkins The June 21, 1991 letter stated that

> "DOE believes further evaluation of the NBTF is appropriate. To do so, we believe a 1-year NBTF Project Definition Phase should be undertaken to achieve: 1) further refinement in the NBTF design, schedule, and cost estimate, and 2) the development of an acquisition strategy for the possible construction and operation of the NBTF."

In 1991, a $2 million request was considered within the DOE as part of the Department's FY 1993 budget. Funding constraints forced the Secretary to remove that request. This year, the College and the Society worked to restore this funding in response to the Secretary's recommendation. A $2 million Energy and Water Appropriation for the siting and development of the NBTF was included in the FY 1994 appropriations (PL103-136).

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[3] Health and Environmental Research Advisory Committee (HERAC), Office of Energy and Research, U. S. Department of Energy. August, 1989. Review of the Office of Health and Environmental Research Program, "Nuclear Medicine". Washington, D.C.

[4] U.S. Dept. of Energy, Los Alamos National Laboratory, May 1989. Proceedings of the DOE Workshop "The Role of a High-Current Accelerator in the Future of Nuclear Medicine. " Los Alamos, New Mexico: Conference LA-11576-C.

The estimated cost of the facility does not compare to the significant contributions the NBTF will surely make. The NBTF will train future scientists and restore America's strength in biomedical science and technology. Some of the most exciting areas of cancer research utilize radioisotopes. An NBTF is needed to produce short lived isotopes for this exciting work.

This facility cannot fulfill its mission without assistance from the federal government. Although the NBTF would recoup a portion of its operating costs through the production and sale of isotopes, the income from these activities should not be forced to support the research and education activities, much less recover the cost of construction of the facility. The ACNP and SNM believe that if the NBTF is to fulfill its mission, it cannot be a for profit venture, it cannot be expected to generate the venture capital necessary for construction nor sufficient income to completely offset its continuous operation. Research and clinical activities that depend on these radionuclides should not be sacrificed.

The Dept. of Energy recently released a Request For Proposals to begin the development of the National Biomedical Tracer Facility. The constraints included in the criteria for selection, particularly the demand that this facility be operated in what amounts to full cost recovery for its operation and construction, makes it impossible to achieve construction and operation of the National Biomedical Tracer Facility. If this requirement is mandated by Federal law, then the law must be changed to reflect the reality of the situation. When these isotopes developed by the R&D program at the NBTF become commercially viable then, as has repeatedly happened historically in the DOE sponsored Nuclear Medicine program, the technology will be transferred to industry and the marketplace will bear the costs of production.

No other DOE facility in the nation is constrained to recover the cost of its activities in research and development, education, and training by the sale of its services, not to mention the cost of constructing those facilities. Ironically, Nuclear Medicine -- a sterling success story in technology transfer, as mentioned before, -- has been made a victim of its own success.

IV. REACTOR PRODUCED RADIONUCLIDES

The situation regarding the supply of fission derived Mo-99 (“fission moly”) is abominable.

Fission moly is the parent of 99mTc in the 99Mo/99mTc generators which provide the source for all of the 99mTc used in U.S. Nuclear Medicine laboratories and those world wide. 99mTc forms the backbone of Nuclear Medicine in this country as over 80% of the clinical scintigraphic imaging studies are performed using 99mTc labeled radiopharmaceuticals. This amounts to approximately 30,000 imaging procedures every day. There is currently only one supplier of fission moly for the U.S. (Nordion Inc. located in Canada). Any interruption in the supply would be devastating to the Nuclear Medicine community causing our patients to either forgo necessary procedures or alternate procedures that are not specific enough or able to produce the desirable results.

Prolonged interruption of the supply would result in the loss of an area of expertise that depended on the routine availability of fission moly (including radiopharmaceutical manufacturers, gamma-camera manufacturers, health care workers, central radiopharmacies, and others). Clearly, reliance on a single source for a radionuclide is courting disaster for patients and workers throughout the U.S. For this reason, the ACNP and SNM feel that a second source, located in the U.S. for this critical radionuclide be identified and developed as soon as possible.

It is urgent that DOE and U.S. radiopharmaceutical industries work together to arrive at an appropriate solution, since the solution to this problem has been difficult. Utilization of the Omega West Reactor at LANL to produce fission moly appears to have ceased to be an alternative. If this reactor never restarts it is critical that a task force be established with representatives from DOE, radiopharmaceutical manufacturers, and other interested parties to identify a solution as soon as possible. This country **cannot** afford any further delays.

Other Reactor-Produced Radioisotopes:

There are several reactor produced radioisotopes with properties well suited for medical applications. Since most of the radionuclides produced in reactors are beta-particle emitters, they are used for radiotherapeutic applications. When coupled with highly specific biomolecular targeting agents, they have and will produce sophisticated therapeutic drugs. Several of these radionuclides are already being used for treatment of patients using new and developing drugs. For example, 89Sr was recently approved by the FDA for palliation of bone cancer pain. Two other new agents capable of alleviating pain in patients with metastatic bone cancer based on 153Sm and 186Re are under clinical study for approval. There are two sources in North America--Nordion, Inc- and the Missouri University Research Reactor (MURR)-- for these latter two short lived (i.e. approximately 2 day and 4 day half-lives) radioisotopes that are adequate for on-going and future clinical studies with respective bone therapy agents. The costs of these radionuclides and several others is prohibitively high now, since only small quantities are used during the research period. These studies need continued federal support until the approval process is complete and full cost recovery can be achieved in the marketplace.

Another isotope of rhenium, 188Re, has tremendous potential for use in therapy as well. It is produced in a generator system from 188W, similar to the system that produces 99mTc. The development of this isotope has been limited by the unique requirements for a reactor to produce it. The potential of this isotope demands that we make it available routinely.

Another area of concern is the ability of the current domestic supply of longer lived radioisotopes for biomedical research and applications to remain competitive since some overseas reactor operations are government-subsidized. For example, 32P, 35S, 191Ir, 125I, and other radionuclides are being routinely supplied by U.S. reactors and Nordion, Inc. These radionuclides are crucial for an enormous amount of basic, applied, and clinical studies throughout this country. In fact, the major thrust of the Human Genome Project and other state of the art studies in molecular biology would be impossible without these radionuclides.

U.S. reactors currently must bring in sufficient revenues to cover operational costs of the reactors. Several foreign reactors (e.g., Petten-Holland, Australia, Belgium, and France as well as others in Eastern Europe) have an enormous competitive advantage. Since they are being subsidized by their governments, income from sales of isotopes they market need only cover the costs of administration, preparation, and shipping. If the U.S. is to continue to be involved in production of reactor produced isotopes for research and medicine, as well as a supplier for domestic corporations, some assistance will be necessary. The relatively modest amount of assistance required would have the enormous benefits of maintaining an adequate supply from one or more U.S. sources.

V. STABLE ENRICHED ISOTOPES

A reliable supply of enriched, stable isotopes is also essential as part of the infrastructure of medical isotope production. They are used to examine fundamental scientific problems in physics, chemistry, biology, nutrition, agricultural and environmental research. Second, they are used as targets in reactors and accelerators to produce research radioisotopes of sufficient purity to be used in humans, animals, or in other investigations. These enriched stable isotopes are also the feedstock for commercial vendors to produce radiopharmaceuticals that are used routinely in the clinic for diagnosis and therapy as well as in laboratory testing.

Thallium-201, used in the diagnosis of heart disease, is produced from enriched stable targets in low energy accelerators. Gallium-67 used to diagnose infection, soft tissue tumors and other diseases is produced using an enriched stable target. Iodine-125 which is used in a wide variety of laboratory tests, in investigational therapy for brain cancer, and in other forms, also is produced using an enriched stable target in a reactor. Strontium-89, the new bone therapy agent, is made from a stable enriched target. All of these are routinely used in the clinic. Other new radionuclides, such as 188Re, require enriched stable isotopes for their production. And many of the isotopes that we will tell you about in the next 10 years also require enriched stable isotopes as targets.

While stable enriched isotopes can be stored indefinitely, the supply is finite and there is currently no immediate plan for their replenishment in the U.S.. Analogous to the situation with fission moly production, Russia is the only country producing stable, enriched isotopes. The U.S. is dependent upon a sole source and must rely on the political and economic stability in that country to continue production, but long-term continuity is a precarious situation. Thus, it is essential that DOE maintain the capability to produce and supply these stable isotopes,

VI. EDUCATION AND TRAINING

In the past, the U.S. was the focal point for training in the nuclear sciences. Our preeminence has deteriorated such that vacant positions for nuclear scientists are often not filled from within the nation. U.S. graduate students and faculty members in Nuclear Medicine must commonly travel abroad to seek advanced study and training in Nuclear Medicine because research radioisotopes are more readily available in other countries. We face a critical shortage of undergraduate and graduate students, and have become increasingly dependent on foreign-trained students to meet our existing needs.[5]

This activity within the Isotope Production Program has been completely lost in the focus to achieve full cost recovery. Ironically, the graduate students, undergraduate students, and postdoctoral fellows who would contribute to such an effort would also be valuable employees in the industries that result from these activities. They would process the materials for commercial vendors, make radiopharmaceuticals as radiopharamcists, and conduct research on new compounds for the future. We need to insure that a constant supply of these students are educated and trained. This activity is completely lost if one has to focus totally on a self-sustaining program. Education and training have always been undertaken with the help of support from the federal government, usually as part of the research mission.

VII CONCLUSION

The College and Society understand the severe budget constraints under which the government is operating. Previous research activities funded by the DOE's Medical Applications Program, designed to enhance the applications of both radioactive and stable isotopes, have made major contributions to the heath care delivery system in the United States and provided spectacular examples of the transfer of technology in the area of Nuclear Medicine and medical research in general.

The facts are clear. In order to continue the progress and momentum achieved in the field of Nuclear Medicine, it is imperative that funding for research efforts be increased and radioisotope production be maintained. We also caution Congress against ignoring the warning signs for a complete breakdown of the radioisotope infrastructure. This would put the U.S. in a situation where we will be totally dependent upon foreign suppliers for the radioisotopes used in this country for research and medical applications.

The second nugget of wisdom that I remembered in considering this area is well known to members of this body. One of the most celebrated Speakers of the House is famous for saying: If it ain't broke, don't fix it. What we have here is axiomatic. The system was working, but we decided to fix it. Now, the Isotope Production Program is definitely broke, in every sense of the word. Let's admit that fact. And let's recognize that we can fix it. I am here to assure you that the Society of Nuclear Medicine and the American College of Nuclear Physicians is ready to assist DOE and the Congress in putting this essential activity back on track. The results are not intangible gains in human wisdom--they are improvements in the health and well-being of the citizens of this country.

Thank you.

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[5] National Research Council, National Academy of Sciences, 1988. Training for Chemists in Nuclear Medicine, Nuclear Industry, and Related areas. Washington, DC, National Academy of Sciences

Mr. SYNAR. Mr. Brown.

STATEMENT OF ROY W. BROWN, DIRECTOR, REGULATORY AND PROFESSIONAL AFFAIRS, MALLINCKRODT MEDICAL, INC., ST. LOUIS, MO, ON BEHALF OF THE COUNCIL ON RADIONUCLIDES AND RADIOPHARMACEUTICALS [CORAR], INC.

Mr. BROWN. Thank you, Mr. Chairman. My name is Roy Brown. I am director of Regulatory and Professional Affairs for Mallinckrodt Medical in St. Louis. I am testifying today on behalf of the Council on Radionuclides and Radiopharmaceuticals, Inc., or CORAR.

CORAR is an association of companies with common business interests in radionuclides, radiochemicals, and other radioactive products primarily used in medicine and life science research and radiopharmaceuticals. The member companies of CORAR supply vitally important radiopharmaceuticals and radioactive material to physicians and research facilities throughout the world.

These radiopharmaceuticals are used in over 10 million medical procedures each year in the United States alone. These nuclear medicine procedures provide physicians important diagnostic information for patients with cancer, heart disease, AIDS, and other very serious and life-threatening conditions.

Nuclear medicine technology was born out of the early days of nuclear weapons research and the Manhattan Project. After the end of World War II, there was a significant interest in the power of healing that might be gained by harnessing the power of the atom. The infrastructure of facilities and research personnel that the National Laboratory system brought to us was instrumental in providing us important isotopes for clinical research. As a result, the United States became the leading center of excellence of this important area of medicine.

The radiopharmaceutical industry today is small in comparison to the vital role it plays in the accurate diagnosis and delivery of health care. Total annual sales for our industry are $450 million. By comparison, the traditional pharmaceutical industry has annual sales of almost $70 billion. In fact, the annual sales of a single antiulcer drug, Zantac, are more than double that of the entire radiopharmaceutical industry.

CORAR is vitally concerned with the maintenance of reliable, cost effective radioisotope and highly enriched nonradioactive target material needed to manufacture such products. On behalf of the members of CORAR, I want to thank you for holding this hearing today to investigate the reliability of this supply.

The radioactive components used in medical radionuclides and radiopharmaceuticals originate from two basic sources, reactor-produced radioactive isotopes and cyclotron-produced radionuclides. Over 80 percent of the nuclear medicine procedures in the United States use technetium-99m which originates from a reactor produced raw material called molybdenum-99 or moly-99. Moly-99 is produced most efficiently in a nuclear reactor. With the complexity and cost of operating a nuclear reactor, our companies have relied on commercial and research reactors to produce this critical raw material. At this time, the only major producer of moly-99 in North

America is Atomic Energy of Canada Limited or AECL, a Canadian Government owned and operated reactor. Nordion International in Kanata, Ontario receives the moly-99 from AECL where it is processed and purified. The purified moly-99 is shipped from Nordion to all the U.S. manufacturers where we further process the liquid, dilute it to specifications and formulate it into generators. The AECL reactor that Nordion receives the moly-99 from is 30 plus years old.

Until recently, AECL has been constructing a replacement for the old NRU reactor named Maple-X. We have recently learned that AECL does not plan to complete the Maple-X reactor due to a financial disagreement between Nordion and AECL. Our industry is concerned that we have only one major supplier of medical radionuclides in the nuclear medicine community and that supplier is located outside the United States.

CORAR believes that in order for the industry to have a secure supply of moly-99 and other necessary radionuclides with adequate backup supply, the DOE should develop the technology and capability to produce these radionuclides. The other 20 percent of nuclear medicine procedures use radionuclides that are produced in particle accelerators or cyclotrons. All of the major manufacturers have their own cyclotrons. The essential raw material for this type of radionuclide production is highly enriched stable or nonradioactive isotopes. These stable isotopes can be manufactured by devices called calutrons. Prior to August 1991, DOE produced stable isotopes in their calutrons at Oak Ridge National Lab. The stable isotopes available from DOE were priced as much as 25 percent higher than material available from other sources. DOE's market share declined due to their unfavorable pricing until such time they were forced to shut down the Oak Ridge operation.

Our industry will continue to need these stable isotopes as target material for our cyclotrons in order to produce the balance of radionuclides not available from nuclear reactors. CORAR feels it is necessary for DOE to stay in the stable isotope business through revitalizing the calutrons at Oak Ridge or employing newer technology to produce these materials.

I would like to make a brief statement with regard to the National Biomedical Tracer Facility or NBTF. CORAR members believe it has the potential to become a very important tool in the development of new radiopharmaceuticals and supply the research community radionuclides that are not commercially available, and we support the operating principles as outlined in the mission statement developed at Purdue in 1992.

In conclusion, let me tell you again how much CORAR appreciates the opportunity to participate in this hearing today and we look forward to working with you to insure that nuclear medicine continues to be available to everyone.

[The prepared statement of Mr. Brown follows:]

TESTIMONY OF
ROY BROWN, CHAIRMAN
COUNCIL ON RADIONUCLIDES AND RADIOPHARMACEUTICALS, INC.

Thank you Mr. Chairman. My name is Roy Brown. I am Director of Regulatory and Professional Affairs for Mallinckrodt Medical, Inc. I am testifying today on behalf of the Council on Radionuclides and Radiopharmaceuticals, Inc. or CORAR. CORAR is an association of companies with common business interests in radionuclides, radiochemicals and other radioactive products primarily used in medicine and life science research, and radiopharmaceuticals. The member companies of CORAR supply vitally important radiopharmaceuticals and radioactive material to physicians and research facilities throughout the world. These radiopharmaceuticals are used in over 10 million medical procedures per year in the U.S. alone. These nuclear medicine procedures provide physicians important diagnostic information from patients with cancer, heart disease, AIDS, and other very serious and life threatening conditions.

Nuclear medicine technology was born out of the early days of nuclear weapons research and the Manhattan Project. After the end of World War II, there was significant interest in the power of healing that might be gained by harnessing the power of the atom. The infrastructure of facilities and research personnel that the National Laboratory system brought us were instrumental in providing important isotopes for clinical research. As a result, the US became the leading center of excellence of this important area of medicine.

The radiopharmaceutical industry today is small in comparison to the vital role it plays in the accurate diagnosis and delivery of health care. Total annual sales for our industry are 450 million annually. By comparison, the traditional pharmaceutical industry has almost 70 billion in annual sales. In fact, the annual sales of a single anti-ulcer drug are more than double that of the entire radiopharmaceutical industry.

CORAR is vitally concerned with the maintenance of reliable, cost-effective radioisotope and highly enriched non-radioactive target materials needed to manufacture such products. On behalf of the members of CORAR, I want to thank you for holding this hearing today to investigate the reliability of that supply.

Radionuclide Supply

The radioactive components used in medical radionuclides and radiopharmaceuticals originate from two basic sources--reactor produced radioactive isotopes and cyclotron produced radionuclides. Over 90% of the nuclear medicine procedures use Technetium-99m (Tc-99m) which originates from a reactor produced raw material called

Molybdenum-99 (Mo-99). Mo-99 is produced most efficiently in a nuclear reactor. With the complexity and cost of operating a nuclear reactor, our companies have relied on commercial and research reactors to produce this critical raw material. At this time, the only producer of Mo-99 is Atomic Energy of Canada Ltd, a Canadian government owned and operated reactor. Nordion International in Kanata, Ontario receives the Mo-99 from AECL, where it is processed and purified. The purified Mo-99 is shipped from Nordion to all of the U.S. manufacturers where we further manipulate the liquid Mo-99, dilute it to specifications, and incorporate it into generators. This final product is a Technetium Generator, weighing from 24 to 60 pounds, and about the size and shape of an ice bucket. The finished generator has a usable life of about 8-10 days, and must be shipped immediately due to its short half-life. Nuclear pharmacists use these generators to create the unit doses that are finally injected in the patient prior to imaging.

Until 1990, Cintichem operated a reactor in New York state, producing Mo-99 for our industry. In 1990, the facility was shut down and is currently being decommissioned.

Other reactor sites located in Europe and other parts of the world do not have the technology nor the capacity to fill our industry's needs. This has led to the current situation in which the Canadian reactor is the only facility that is capable of supplying the needs of the U.S. market.

The AECL reactor that Nordion receives the Mo-99 from is 30+ years old. Until recently AECL had been constructing a replacement for the old NRU reactor. That reactor, named Maple-X, was intended to be a state of the art reactor that would produce the critically needed Mo-99 well into the 21st century. The member companies of CORAR and the entire nuclear medicine community in the U.S. have been very concerned over our reliance on the aging NRU reactor, but the prospect of the Maple-X reactor coming on-line had suppressed these concerns. We have recently learned that AECL does not plan to complete the Maple-X reactor due to a financial disagreement between Nordion and AECL. This dispute may be resolved in the current arbitration between these companies, but a decision not to complete the Maple-X could be devastating to the practice of nuclear medicine in the U.S. and around the world.

Our industry is concerned that we only have one major supplier of medical radionuclides to the nuclear medicine community, and that supplier is located outside the U.S. As a result, we are working to develop other means to insure that there is an alternative supplier to AECL. For example, Mallinckrodt Medical is currently constructing a Mo-99 production facility in the Netherlands, that will help ease the worldwide lack of adequate backup. This facility is due to open in 1995. Its source of raw Mo-99 will be nuclear reactors owned by various European countries. However, as currently planned, the Netherlands facility will only produce enough Mo-99 to supply Mallinckrodt's needs.

CORAR believes that in order for the industry to have a secure supply of Mo-99 and other necessary radionuclides with adequate backup supply, the DOE should develop the technology and capability to produce these radionuclides. Furthermore, it seems apparent that DOE cannot operate their Isotope Production and Distribution Program on a self-sustaining basis as required by Public Law 101-101. One option that has been discussed and we believe merits further investigation is the possibility of DOE providing backup to Nordion by routinely filling a small percentage of their Mo-99 orders. The proposal would call for DOE to irradiate AECL target material in one of DOE's reactors, and then send the irradiated targets to Nordion for processing. While this arrangement would not totally eliminate our dependence on Canada, it would at least eliminate our dependence on their aging reactor.

It may be important to note here that part of the problem with finding a nuclear reactor to produce Mo-99 is the small amount of time Mo-99 production would take on any one reactor. For example, if Mo-99 production was the only thing that the Canadian Chalk River Reactor was being used for, it would only be utilizing 4-5% of it's potential output. If DOE's Omega West, a much smaller reactor, was used to produce Mo-99 it would have at least 40% excess capacity. Therefore, while Omega West could become an essential production facility for Nuclear Medicine in the US, it would never be adequately utilized with Mo-99 as its only product.

Highly Enriched Stable Isotopes

The other 10% of nuclear medicine procedures use radionuclides that are produced in particle accelerators, or what we call cyclotrons. All of the major manufacturers have their own cyclotrons. The essential raw material for this type of production is a highly enriched stable or non-radioactive isotope. These stable isotopes can be manufactured by devices called calutrons. Prior to August, 1991, DOE produced stable isotopes in their calutrons at Oak Ridge National Lab. The stable isotopes available from DOE were priced as much as 25% higher than material available from other sources. DOE's market share declined due to their unfavorable pricing until such time they were forced to shut down the Oak Ridge operation.

Our industry will continue to need these stable isotopes as target material for our cyclotrons in order to produce the balance of radionuclides not available from nuclear reactors. The industry is currently purchasing some of these stable materials from the Russian government at a greatly reduced price. Although DOE has a stockpile of stable isotopes, their material is overpriced.

It is important for our industry to have material available from more than one supplier. For DOE to be a viable supplier of stable isotopes to our industry, we need a reliable product at a competitive price.

CORAR feels it is necessary for DOE to stay in the stable isotope market through revitalizing the calutrons at Oak Ridge, or employing newer technology to produce these materials.

National Biomedical Tracer Facility

The National Biomedical Tracer Facility or NBTF, has the potential to become a very important tool in the development of new radiopharmaceuticals, and supply the research community radionuclides that are not commercially available. In the early days of the Atomic Energy Commission, one of the stated goals of the Act (1946) was, among other goals, to foster and support research in biology and health as well as electric power production. Oak Ridge National Laboratories was an example of how well this goal was accomplished. During the height of the Cold War, in addition to their primary defense mission, they produced and distributed isotopes that fostered current state of the art and science. Among these were the Iodine's, Sulfur compounds, Carbon 14, Tritium and Phosphorus isotopes that are taken for granted today. While today we view these and other isotopes as normal high tech commodities, they might not have been available as vital tools for the researcher or the clinician had it not been for the foresight of the early AEC leaders. Equally important, these national laboratories were natural magnets attracting the brightest and best people to learn and then go out and teach, and this is a key issue: The NBTF must return to the lessons of the past and provide major training and educational facilities for the leaders and teachers of the future.

Our industry supports the NBTF operating principles as outlined in the mission statement developed at Purdue University in 1992. The production of radionuclides at the NBTF would be limited to those materials that are not commercially available. We believe that the NBTF is an important national priority and, as such, should not be required to produce operating margins in terms of dollars, but should obtain long-term government funding to yield knowledge and products that will spawn significantly higher returns in the provision of cost effective healthcare, tax base enhancement and new jobs and protection of the environment.

For these reasons, we must properly fund the NBTF project, recruit and select the superior persons to staff it and not limit ourselves to the areas of radioisotopes alone. Stable isotope separation capability in the U.S. is not adequate and we are dependent on equipment using 1930's technology.

In conclusion, let me tell you again how much CORAR appreciates the opportunity to participate in this hearing today, and we look forward to working with you to insure that nuclear medicine continues to be available to everyone.

Mr. SYNAR. Dr. Trevena.

STATEMENT OF DR. IAIN TREVENA, VICE PRESIDENT, ISOTOPE PRODUCTS, NORDION INTERNATIONAL, INC., KANATA, ONTARIO, CANADA

Dr. TREVENA. Thank you. I am Iain Trevena, vice president of Nordion International. Mr. Chairman, I would like to thank you for giving me the opportunity to appear today. I would like to very briefly summarize the statement that I provided for the record.

I would first like to address the issue of reliability of supply by considering three factors: Our current capacity, our anticipated future capacity and other worldwide sources for commercial use of the isotopes in question, but with specific regard to molybdenum-99 that has been talked about earlier.

Regarding our current capacity, Nordion has been in the business of making and selling isotopes for nearly 50 years. Today we are the leading supplier of reactor isotopes for medical diagnostic applications, in large part because our customers trust Nordion as a consistent, dependable supplier. We take pride in what we do, and during an 8 week strike in 1991, our professional staff maintained production and there was no interruption in supply. Throughout 1992 and 1993 we supplied our customers with product from a single reactor, the NRU reactor located in Chalk River. This reactor is working to our complete satisfaction. Although it does provide a public research function, it has the capability to provide additional production if warranted and has on occasion supplied the whole world's supply of molybdenum-99.

Under the terms of the Canada-United States Free Trade Agreement, we regard the United States market as a borderless extension of our Canadian base. We welcome the open market access that the FTA provides and offer unconditional, nondiscriminatory security of supply in return.

Regarding future capacity, the privatization of Nordion was structured in such a way as to envision the decommissioning of the then standby reactor, NRX, and Atomic Energy of Canada's construction of a new reactor, Maple-X, dedicated to isotope production. Maple-X has passed the rigorous design review and awaits imminent award of a construction license. However, actual construction of Maple-X is not likely to proceed until the outstanding legal issues between Nordion and AECL are resolved. These proceedings are simply an issue of money. They involve differing interpretations of the extent of the Canadian Government's financial obligations to build Maple-X under the terms of Nordion's purchase by a private company, MDS, from the Government of Canada itself.

Please understand, both Nordion and AECL believe that Maple-X can and should be built. We at Nordion are confident that this commercial dispute will be resolved in a timely manner. Until Maple-X is fully operational, NRU will meet our customer's needs.

Regarding other sources of supply, the worldwide picture for reactor isotopes will change dramatically over the next 12 to 18 months. Mallinckrodt is expected to be producing molybdenum-99 in Europe in early 1995, and sometime in 1996 expect to be able to produce their own United States requirements.

In Belgium there is a company called IRE which uses four European reactors to supply currently about 15 percent of the world's supply. They plan to be able to move to 50 percent of that supply in January of next year. It is about a couple of months away.

South Africa makes its own fission product moly and has the capacity to gear up to perhaps 30 percent of the world's needs. No company likes to lose business. We welcome fair competition and trust this subcommittee will take these changing factors into account while weighing the need for what may well be heavily subsidized domestic commercial scale production of molybdenum-99.

I would like to deal with the issues of subsidies which you addressed in your letter. The NRU reactor does serve a dual production and national research role. However, Nordion pays AECL for products and services on terms contained in an agreement regarding Nordion's sale to a private company, MDS.

These terms in this agreement allocate what was believed to be an equitable share of production costs and overhead costs of the product. Nordion receives no subsidy for its commercial isotope products. However, regarding new product development, Nordion and all other North American companies who conduct research in Canada are eligible on a nondiscriminatory basis to receive Canadian Government grants. These, however, would be repaid over time should a product become successful.

In closing, Mr. Chairman, I would like to point out that I recognize the very—we recognize the very great importance of molybdenum-99 to the market. It is a $50 million market world wide which is quite small and that needs to be recognized as you look at how you supply that market. The entry costs are high. Infrastructure required for moly is high. Treatment of waste costs is a serious consideration. Because of that high volume that is required in order to achieve a low price for the customer and a fair rate of return for the producer, long-term reliability of supply is a function of all these factors. We have been and intend to remain a fully reliable participant in this exciting marketplace. Thank you.

[The prepared statement of Dr. Trevena follows:]

STATEMENT BY DR. IAIN TREVENA

VICE-PRESIDENT, ISOTOPE PRODUCTS

NORDION INTERNATIONAL INC.

BEFORE THE HOUSE GOVERNMENT OPERATIONS SUBCOMMITTEE
ON ENVIRONMENT, ENERGY AND NATURAL RESOURCES

DECEMBER 6, 1993

NORDION
INTERNATIONAL INC.

ISOTOPE SUPPLY CAPABILITY

Nordion, whose main place of business is in Kanata, near Ottawa, Ontario has been in the business of producing and marketing radioisotopes for nearly 50 years. The initial focus of the company was reactor isotopes, but in 1980 Nordion made a decision to get into the production of accelerator produced isotopes and as a result established a facility in Vancouver at TRIUMF (Tri-University Meson Facility). In 1991, Nordion acquired some of the assets of L'Institut National des Radioéléments (IRE) in Belgium, and as a result gained access to both reactor and accelerator isotope capabilities in Europe.

Nordion's Origins as a Private Sector Company

It is useful to consider Nordion's current role as the leading supplier of reactor isotopes for medical diagnostic applications in the context of the company's origins. Originally, Nordion was the Radiochemical Company (RCC) of Atomic Energy of Canada Limited (AECL). As the RCC, it processed and sold reactor radioisotopes. RCC paid the Research Company of AECL (AECL-RC) for reactor and processing services and was expected to generate an earnings stream for AECL. By the early 1980's, the RCC had become a sound commercial enterprise, and AECL realised that it would fare better in the private sector. AECL senior management saw the benefits of spinning off RCC and using the resources from such a sale to further develop their core business. It was believed that there could be other spin-offs in the future.

In order to prepare the RCC, which had been re-named "Nordion", for privatisation, in 1986, a 25 year agreement was struck between AECL-RC and Nordion that would provide a mechanism for Nordion to pay for the services provided by the AECL Research Company. This agreement to supply isotopes was amended in 1988 and 1991. It was premised upon the construction of a new reactor dedicated to isotope production, Maple-X. At the time of the sale of the shares of Nordion, the proceeds flowed to the Government Treasury. Once AECL were no longer receiving any of the profits from the isotope business, AECL apparently found itself unable to support the significant infrastructure required. AECL's attempts to secure some of the proceeds of the sale were unsuccessful.

Since they were unable to obtain anything from the sale of what had been part of their company, AECL chose another way to secure additional funding. Accordingly, when AECL and Nordion started routine senior management communication meetings in the spring of 1992, AECL indicated that they did not believe that the ongoing revenues that they would receive from Nordion would be sufficient to support the funding required for molybdenum-99 business. Since that time, both Nordion and MDS have been requesting that MDS, Nordion, AECL and the Government of Canada meet to resolve the situation. Since MDS paid the Government of Canada $165 million for a business whose major asset was the isotope supply agreement with AECL, MDS would look to the Government of Canada, as AECL's shareholder and the vendor of Nordion, to use the proceeds of the sale to resolve AECL's cash problem. Unfortunately, there has as yet been no resolution acceptable to both parties.

This issue will be resolved in a Canadian court either by settlement or arbitration. Until such resolution, AECL has decided not to continue with the construction of the Maple-X reactor. However, both AECL and Nordion recognise the need for Maple-X to ensure long term reliable supply of reactor isotopes. The Maple-X building is complete and all the required design and regulatory hurdles have been met to permit AECL to complete the construction. Work on the Maple-X reactor was stopped because of funding issues, not because of a technical or safety problem with the reactor.

Despite the disagreement that AECL and Nordion are having over significant financial matters, AECL has made public on several occasions its intent to continue to supply isotopes reliably with its NRU reactor.

Product Costing - Subsidies

Nordion itself receives no subsidies, and in the costing of its products ensures that each product or product group is responsible for its operational overhead. Nordion obtains its reactor isotopes from AECL and pays for the product on the basis of a contract that was initially prepared in 1986 and subsequently modified in 1988 and 1991. In 1988, Nordion was still part of AECL, and the contract was established to ensure a fair return to both parties taking into account all costs, including overhead. (The 1991 version simply puts certain restrictions on Nordion.) MDS paid the Government of Canada $165 million for Nordion and the supply contract was a major asset.

Reactor Produced Isotopes

At this point it is useful to consider Nordion's capability to supply reactor isotopes, with special reference to molybdenum-99.

The facility requirements for high level production of fission molybdenum-99 are extremely demanding. These requirements may be summarised as follows:

- High flux (1×10^{14}) reactor;
- License to hold highly enriched uranium-235;
- Heavily shielded processing facilities with adequate nuclear ventilation;
- Radioactive waste processing and waste disposal facilities;
- Ability to meet current Good Manufacturing Practices requirements; and
- Fleet of Licensed Type B(U) shipping containers.

Because the infrastructure required to ensure conformance to all appropriate regulations is significant, and as the world market is relatively small, the producer of molybdenum-99 requires a high volume of business to ensure commercial viability.

Currently, Nordion International Inc. is the only supplier of molybdenum-99 in North America. Highly enriched uranium-235 targets are irradiated in the NRU reactor at the AECL Chalk River research facility. A first stage process separates molybdenum-99 from the bulk of the fission products. The crude material is then transported by road, a journey of two hours, to Nordion's facility in Kanata where product processing, quality control, packaging, and dispatch to customers takes place. A typical batch of molybdenum-99 measures 5000 - 6000 curies, and Nordion processes several batches a week. Shipments to customers are made every day, except Saturday. Nordion maintains a charter aircraft to ensure timely deliveries to customers in the United States.

A supplier of molybdenum-99 needs to be able to meet the needs of its customers: consistent product quality, availability on specific days of the week throughout the year, and minimum decay losses to minimise cost. In addition to meeting these needs, the supplier must also be able to respond to unplanned requirements. Nordion ensures this capability by some overproduction within the reactor to provide additional targets for processing.

NRU Reactor

The NRU reactor was shut-down for nearly all of 1991 following a pipe failure. During this period, extensive testing was carried out on all the critical systems before the reactor was restarted at the end of 1991. Reliable supply was maintained by NRU throughout 1992 and 1993. The reactor has been shut-down from time-to-time to carry out maintenance and also to carry out experiments related to AECL's nuclear research program. Supply was ensured by building up target inventory in advance. We have been told by some of our major customers in the United States that our delivery record on molybdenum-99 from Canada to their production operations is better than their own delivery record from cyclotron isotopes that they produce themselves in-house.

Back-up Reactors in North America

In spite of the excellent track record that Nordion and AECL have achieved with supply from NRU, Nordion has recognised that customers have concerns about the dependence on one reactor - now that the decision to shut-down NRX has been made. As a result, in order to obtain back-up capability prior to the start-up of Maple-X, Nordion has considered the irradiation of highly enriched uranium-235 targets at a number of locations: McMaster University in Hamilton, Ontario; MURR in Missouri; HFIR at Oakridge, Tennessee; the Omega West and Sandia reactors in New Mexico; the ATR in Idaho; and the FFTF in Hanford. The McMaster and Missouri reactors were considered to be the most promising for this purpose, but production would not be available until two years after a decision to proceed was made, because of the time required to carry out certain specific modifications and meet regulatory requirments. Of the U.S. Department of Energy (DOE) reactors, only the Omega West and Sandia reactors could be put into a position to irradiate targets at a cost the industry could bear. However, Omega West is currently down for repairs, and the Sandia reactor is able to meet only a little more than 10% of Nordion's needs. Nordion's plan in this regard was to be responsible for the cost of this back-up arrangement with DOE.

Current Production Capability in Europe

In Europe, the major manufacturer of molybdenum-99 is the Institute Nationale des Radioéléments (IRE), located in Fleurus, Belgium. IRE is not a Nordion controlled entity. Nordion does, however, have an agreement to sell its products on a non-exclusive basis. IRE can use any of four reactors for the irradiation of targets: BR-2 in Belgium; SILOE and OSIRIS in France; and HFR in Petten, Holland. Consideration is being given to using other reactors in order to increase supply capability.

For IRE's production, no processing is carried out at the reactor sites. The irradiated uranium-235 targets are transported by road in heavily shielded containers to the facilities at Fleurus which meet the requirements summarised earlier. The fission waste is processed in Belgium by the national authorities. Finished product molybdenum-99 can be distributed to customers throughout the world by Nordion's European operation, which is located on the same site in Fleurus.

Currently, IRE's capability is significantly less than that of Nordion, but by early 1994 it is expected that IRE will be capable of producing 50% of the world's molybdenum-99 requirements. Increasing this capability to even higher levels is being evaluated.

In the implementation of higher production capability, IRE had to consider a number of issues: the capability of the reactors to handle additional target; the individual schedule of the reactors and their ability to respond quickly in a back-up mode; and the processing limits of the facilities with special reference to radioactive releases that may accompany higher level processing.

The table below provides a summary of the isotope production reactors in Europe. Simple service irradiations, such as may be required for the production of strontium-89 may be carried out in a number of these reactors and a list of such product capabilities has not been made.

Nordion has clearly demonstrated a capability to distribute product around the world from Canada. Nordion's European operation can ensure the same capability using molybdenum-99 manufactured by IRE. In a back-up situation, IRE would be provided with Nordion's licensed shipping containers.

Future Supply Capability from Europe

Molybdenum-99 production capability in Europe will be increased in early 1995 when Mallinckrodt plans to start up production. Mallinckrodt does extensive radiopharmaceutical manufacturing at the Petten reactor site, and is in the process of building facilities for molybdenum-99 production at that site. Targets would be irradiated at the HFR reactor in Petten, with, it is believed, back-up provided by other European reactors, most probably the reactor in Studsvik, Sweden.

It is believed that Mallinckrodt's production capability will be equivalent to that of IRE. It is Mallinckrodt's plan to produce product to meet its own European and North American requirements for molybdenum-99. These currently are supplied by IRE and Nordion.

ISOTOPE PRODUCTION REACTORS in EUROPE

Reactor	Power (MW)	County	City/Area	Isotopes Produced/ Targets Irradiated
Studsvik	50	Sweden		Possible fission products
SM2	100	Russia		Ir-192, Co-60
Mayak	?	Russia	Chelyabinsk	Cs-137, Co-60, C-14, H-3, Kr-88
Maria	30	Poland	Warsaw	Possible fission products
HFR	45	Holland	Petten	Mo-99, Xe-133, I-131, Ir-192, Other
OSIRIS	70	France	Saclay	Mo-99, Xe-133, I-131, Ir-192, Other
SILOE	35	France	Glenoble	Mo-99, Xe-133, I-131, Ir-192, Other
BR-2	100	Belgium	Mol	Mo-99, Xe-133, I-131, Ir-192, Other

Accelerator Produced Isotopes

In Canada, at the TRIUMF facility in Vancouver, Nordion owns and operates two compact cyclotrons, a CP-42 and a TR-30. These are used to make thallium-201, iodine-123, indium-111, gallium-67 and cobalt-57. The products are sold to customers who either do not have cyclotrons or who have a shortage of cyclotron capacity. Most recently, Nordion has developed a capability to produce germanium-68 with these machines.

The main TRIUMF cyclotron operates during two 13-week periods a year, generally December - February and May - July, primarily for research purposes. Nordion's collaboration with TRIUMF allows it to utilize the isotope production capabilities of the machine during operating periods, but does not allow it to extend or modify the schedule. As isotope production is, in effect, done parasitically, the costs of production are relatively low.

The TRIUMF cyclotron has a unique facility which can simultaneously bombard twelve solid targets with 500 MeV protons. This facility has been used for many different isotopes in the past, including copper-67, cadmium-109, xenon-127, germanium-68, and strontium-82. Currently it produces strontium-82 by spallation from natural molybdenum metal. Nordion is in the process of putting in additional strontium-82 capability in Europe in order to ensure continuity of supply to our customer in the United States.

The TRIUMF cyclotron also has a 70 - 100 MeV production facility which can operate simultaneously with the 500 MeV beam. This facility can accommodate multiple targets. At present a solid target station on this facility is being used to produce strontium-82 from natural rubidium metal.

Due to the interrupted beam schedule, the TRIUMF 500 MeV and 70 - 100 MeV production facilities are not suitable for the routine production of short lived isotopes. They are, however, very appropriate for achieving year round availability of significant quantities of isotopes with half-lives of one month or more. Shorter lived isotopes can also be produced so that they are available for part of the year. This could suit researchers who are able to schedule experiments to coincide with these periods.

The facilities on the TRIUMF site (500 MeV, 70 - 100 MeV, CP-42, TR-30) have the capability to produce the isotopes required by the North American research community and also can make a significant contribution to the world supply of commercial isotopes.

Decisions on which isotopes to produce are made on economic rather than strategic grounds.

Nordion will provide a product or a service if there is a mechanism to fund the initial development and ongoing production costs, with an acceptable return.

The National Biomedical Tracer Facility Planning and Feasibility Study makes reference to production radioisotopes and research radioisotopes. The area of research radioisotopes is one which requires careful analysis of the supply options to ensure that the research community gets the products that it needs. All the production isotopes mentioned in the Study could be supplied by existing commercial operations.

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Mr. SYNAR. Thank you, doctor. Let me start with you, if I could, and I will ask some questions of the whole panel. As I said in my opening statement, Dr. Trevena, we are heavily dependent upon Nordion for our reactor-produced isotopes and therefore I think there is an interest here about what is going on in Canada and I do appreciate your willingness to testify.

Nordion is privately owned, correct?

Dr. TREVENA. That's correct, yes.

Mr. SYNAR. And AECL is a government corporation; correct?

Dr. TREVENA. That's correct.

Mr. SYNAR. Now, Nordion manufactures the targets and ships them to AECL, then AECL irradiates them in their reactor, ships them back to you where you process them, refine them, package them, and market them, is that correct?

Dr. TREVENA. That's close. It is not exactly right, but it is close.

Mr. SYNAR. Go ahead. What else?

Dr. TREVENA. The actual target is in fact a uranium target so it is actually manufactured by AECL themselves. They are responsible for target fabrication, irradiation and they do a first stage of processing and then partly processed material is shipped by truck to Kanata where the final processing, packaging, and dispatch to a customer occurs.

Mr. SYNAR. I realize that your relationship with AECL is a matter that is in litigation right now and we are very sensitive to that, but in your testimony you state that the NRU reactor, the one that is now being used to produce isotopes, is used for research from time to time by AECL, and that in those cases you overproduce to cover yourselves.

Since it appears that the AECL is actually a user of the reactor to produce your isotopes, does the AECL share the operating cost with Nordion or does Nordion pay the full operating cost?

Dr. TREVENA. No. AECL pays a portion of the costs associated with the production of the molybdenum, those which you might call—so there is a cost center there that is responsible for manufacturing molybdenum and all the things associated with that. So when they are not working there, their costs are still in that cost center.

In addition, the cost structure there is such that recognizing it is a site which has a lot of security attached to it; there are special fire services, bus services, there is a whole infrastructure required for a nuclear site, the 1988 agreement that was set up envisaged payment of what was believed to be a fair share of overhead associated with that, working on that site.

Mr. SYNAR. When we had our hearing in August 1992 there was concern over a labor strike that was pending——

Dr. TREVENA. Right.

Mr. SYNAR [continuing]. With respect to the workers at the AECL reactor. You have had your own labor problems too but right now your problems are with the contract with AECL, is it not?

Dr. TREVENA. Yes. We have a problem with the contract with AECL.

Mr. SYNAR. So that is where we are?

Dr. TREVENA. That's correct, yes. It is a legal issue.

Mr. SYNAR. Nordion had a strike in October 1991, correct?

Dr. TREVENA. That's correct.

Mr. SYNAR. And 1992 was AECL's labor problem, correct?

Dr. TREVENA. That's correct.

Mr. SYNAR. How did you maintain production during the strike?

Dr. TREVENA. In 1991 we used our professional staff to maintain production. We recognize that it is a responsibility of a producer to do what they can to meet the market needs, so——

Mr. SYNAR. How long could you have contained?

Dr. TREVENA. We were in a situation in Nordion to be able to contain indefinitely. We essentially, what we did is we looked at the critical products and initially manufactured only critical products; in other words, products that no one else could make, and in fact during the strike, we in fact started to make products which we would say were noncritical which were just products that we make in addition to other people.

Mr. SYNAR. But you did have to cut back, correct, on some of your product line?

Dr. TREVENA. We cut back on products that other people could manufacture. So we in fact—we used to manufacture radiopharmaceuticals, but we had those manufactured in the United States by our customers.

Mr. SYNAR. I would like to ask unanimous consent to enter in the record exhibit 1.

[Exhibit 1 can be found in the appendix.]

Mr. SYNAR. This is a letter from the Canadian Ambassador responding to some questions we had about the status of AECL's reactors.

Dr. Trevena, we realize that you do not represent the AECL, but it is our understanding that in January 1992, AECL shut down one of its two isotope production reactors, the NRX reactor, and in March of this year, decided to begin decommissioning it.

Now, in 1991, you had a coolant leak in the NRU reactor and you had to use the NRX reactor, the one being decommissioned to maintain production; is that correct?

Dr. TREVENA. That's correct, yes.

Mr. SYNAR. If that were to happen again, it appears that since they are closing down that reactor, there is no backup. The bottom line is you are now dependent upon a single isotope production reactor, the NRU reactor, are you not?

Dr. TREVENA. I think if you are talking about reliability of supply and if the supply has to come from Canada, that's correct.

Mr. SYNAR. So there is no backup reactor at this time capable of supplying all the isotopes from the NRU reactor?

Dr. TREVENA. Not from the NRU reactor.

Mr. SYNAR. So how much could you import from other sources such as Europe if the NRU reactor were shut down tomorrow?

Dr. TREVENA. If it was to shut down tomorrow, we would have some difficulties. If, however, we look to what would be the case in January, the problem would be significantly better.

Mr. SYNAR. Mr. Brown and Dr. Atcher, if that happened tomorrow, if the NRU reactor were forced to shut down, what would the impact be on the United States? Dr. Atcher.

Dr. ATCHER. We would have tremendous difficulty doing the routine clinical nuclear medicine tests that require molybdenum-99. It would be devastating.

Mr. SYNAR. Mr. Brown.

Mr. BROWN. Eighty percent of the 10 million nuclear medicine studies done a year rely on technetium-99m so it would be devastating for the nuclear medicine community.

Mr. SYNAR. Good. Now, Dr. Trevena and Mr. Brown, you both cited actions under way to provide additional isotope capacity. Let's start with the Department of Energy.

As we discussed in 1992, Mr. Brown, the radiopharmaceutical industry helped fund a study of the feasibility of using DOE's reactors to provide that additional source. That study concluded that the Omega West reactor in Los Alamos would be the most feasible, is that correct?

Mr. BROWN. Yes, that's correct.

Mr. SYNAR. But none of the radiopharmaceutical companies were willing to commit money to that project. Why not?

Mr. BROWN. The major manufacturers contributed money for a pilot study to look at the feasibility of using that reactor. At some point in time it was clear to us that it would be difficult to have DOE get that reactor up and running. It would be quite some time before they had an efficient, reliable supply that we could count on.

Mr. SYNAR. High cost and low reliability?

Mr. BROWN. That was a problem, yes.

Mr. SYNAR. Now, Mr. Brown, we understand that some radiopharmaceutical companies had exclusive purchase agreements with Nordion. And Amersham is even a minority partner in Nordion. What role did these considerations play in the industry's decision?

Mr. BROWN. I don't think those played any role at all. Once again, we were looking for a reliable supply so those really did not enter into the decision.

Mr. SYNAR. So even though there was a real concern at the time with obtaining an additional source of supply, the industry turned down Omega West?

Mr. BROWN. Well, once again, we didn't feel it would be a reliable supply.

Mr. SYNAR. As we have just discussed with Dr. Trevena, Mr. Brown, Nordion relies on a government reactor. What is different about the way AECL operates that makes its role more viable compared to DOE?

Mr. BROWN. That is difficult to answer from our perspective. We do know that Nordion is a very, very reliable supplier. We have had very few difficulties with Nordion and their supply over the years.

Mr. SYNAR. What actions did you all take instead of going with Omega West to insure reliability for the United States?

Mr. BROWN. Some of the manufacturers signed long-term agreements with Nordion. Other manufacturers—or another manufacturer, Mallinckrodt, is in the process of developing a moly purification plant in Holland.

Mr. SYNAR. When will that production be available?

Mr. BROWN. Sometime mid 1995.

Mr. SYNAR. 1995. And that facility will be able to supply all of Mallinckrodt's needs?

Mr. BROWN. That is the intent, yes.

Mr. SYNAR. Now, the capability that Mallinckrodt is developing is not a new reactor, is it?

Mr. BROWN. No. It is using government run reactors throughout Europe.

Mr. SYNAR. Now, Mr. Brown, Dr. Trevena's testimony also suggests that you will be using the Petten——

Mr. BROWN. Yes.

Mr. SYNAR [continuing]. Reactor in the Netherlands and it suggests that Nordion, through its relationship with the IRE in Belgium, is going to be using that reactor—and that IRE and Mallinckrodt are going to rely on those reactors in Europe.

Now, the big problem here is the reactor capacity. It appears that what you are adding in Europe is less than the sum of what you say you are going to be able to produce. So how much new capacity are you willing to bring on line in Europe?

Mr. BROWN. The reactors that Mallinckrodt plans on using in Europe are the same reactors that IRE depends on.

Mr. SYNAR. Right. So how much new capacity are you bringing on?

Mr. BROWN. We are not actually going to be making any more moly. Mallinckrodt will get its moly from the operation from——

Mr. SYNAR. So there is no new capacity whatsoever?

Mr. BROWN. No.

Mr. SYNAR. So that won't help supply?

Mr. BROWN. No new reactors coming on line.

Mr. SYNAR. It is overlap?

Mr. BROWN. That's right.

Mr. SYNAR. In both those cases, who owns that reactor, Nordion or Mallinckrodt or somebody else?

Mr. BROWN. The reactors that Mallinckrodt plans on using are government run reactors.

Mr. SYNAR. Government run?

Mr. BROWN. Yes.

Mr. SYNAR. So the basic model around the world for reactor-produced isotopes is a reliance on government-owned reactors; the pharmaceutical industry is not building any reactors itself?

Mr. BROWN. That's correct.

Mr. SYNAR. Dr. Atcher, in your testimony, you suggest that the use of these foreign government owned reactors amounts to a subsidy that DOE cannot compete with if it is going to operate under a full cost recovery system. Do I have that right?

Dr. ATCHER. That's correct.

Mr. SYNAR. All right. Mr. Brown, no pharmaceutical company owns or operates its own reactor. You don't seem willing to make that kind of investment, yet you need reactors to produce medical isotopes you market. Why won't the industry invest in reactors?

Mr. BROWN. The problem the industry has in investing in a reactor is for starters it is very, very expensive. It would be very difficult to site and build a new reactor now. There are certain long-term liabilities associated with reactors dealing with radioactive waste, mixed waste, very difficult waste issues. And for those reasons, the manufacturers have steered away from building their own reactors.

Mr. SYNAR. Dr. Trevena, AECL is in the process of construction of a new isotope production reactor in Canada, Maple-X reactor. It was to be in operation by 1995 or 1996. What percentage of the current production would Maple-X provide?

Dr. TREVENA. It would be able to just take over all the production that we currently make.

Mr. SYNAR. One hundred percent of North American requirements?

Dr. TREVENA. Yes.

Mr. SYNAR. But the construction permit has not even been issued yet, has it?

Dr. TREVENA. It is in construction, in fact, has started. The construction goes in several phases, where it is now is at the fourth stage of the permit. That permit, although it hasn't been granted, is able to be granted and the issue—the reason it hasn't been granted is part of the dispute that we have over AECL which is a matter of money.

Mr. SYNAR. Do I have the facts wrong? The AECL informed the Canadian licensing board last month that it was indefinitely suspending its plan to construct that reactor as a result of that legal dispute.

Dr. TREVENA. That's correct. They made that statement, but I thought the question was whether they could get the license. I am sorry.

Mr. SYNAR. They are not constructing anything?

Dr. TREVENA. They have constructed the building and they stopped. They stopped part way through the construction phase because of the dispute.

Mr. SYNAR. Let me ask unanimous consent to enter into the record at this point exhibit 2.

[Exhibit 2 can be found in the appendix.]

Mr. SYNAR. These are news articles which describe the MDS–AECL dispute. Dr. Trevena, the AECL officials are quoted in these articles as saying that they are under no obligation to complete Maple-X. I realize that you can't again speak for the AECL and that this matter is in litigation, but as you heard in the testimony this morning, a statement that AECL does not have an obligation to continue the Maple-X raises questions, very serious questions, very candidly, about the long-term reliability of our isotope supply from Canada. That dispute will clearly delay Maple-X, if not end it all together. What can you tell us about when this dispute is going to be resolved and what it means for Maple-X?

Dr. TREVENA. Several parts. I will deal with the dispute itself to the extent that I can, given the litigation that is going on. The Government of Canada sold a supply contract to MDS. Under that supply contract, there was a requirement to build—under the agreement of sale, there was a requirement to build Maple-X and MDS is looking for that in resolution and that is why the legal dispute has arisen.

With respect to the delay that AECL is putting on this dispute, we believe that this dispute will be settled no later than mid 1994 and that would put a 6-month delay on Maple-X, given where it is right now in the licensing phase. We should put it on line at the end of 1995.

Mr. SYNAR. Now, assuming that dispute is resolved and Maple-X goes on line as you said, we were interested in that so we asked the Canadian Government whether that remaining reactor, the NRU reactor, would be decommissioned or whether or not they would have a backup reactor. And the answer we got back suggested this had not been determined because of the legal dispute which you just described. Can you give us any feeling for whether or not that reactor is going to be available for backup?

Dr. TREVENA. I guess I am surprised at what they said but I would expect—we believe it will be available for backup.

Mr. SYNAR. OK. We didn't get that out of our correspondence.

Mr. Brown, what is your industry's assessment of the timing and the prospects of Maple-X and how long it will take to resolve the legal dispute?

Mr. BROWN. I am sorry. Once again, you asked how long we think it will take?

Mr. SYNAR. What is your assessment of this Maple-X problem and this dispute?

Mr. BROWN. Well, we are concerned that if the Maple-X reactor is not constructed there will not be an adequate backup to the NRU reactor.

Mr. SYNAR. When do you think it is going to be resolved?

Mr. BROWN. We hope that there is resolution between MDS and AECL and the Maple-X reactor construction continues.

Mr. SYNAR. Dr. Trevena, I guess I ought to give you credit where credit is due. I think you have pretty well described the situation and the concern over it and I think it is pretty good.

Now, DOE is going to testify this afternoon that it is committed to providing additional capacity, but it doesn't say how. Can you tell us what options DOE really has? Mr. Brown.

Mr. BROWN. The way CORAR sees it, we had hoped at one point in time that DOE would modify one of their reactors to be able to produce moly-99 as a backup to Nordion.

Mr. SYNAR. Are you familiar with the recent work DOE did in conjunction with the AECL to investigate the use of other DOE reactors such as the high flux reactor?

Mr. BROWN. No, I am not.

Mr. SYNAR. If we provide that material to you, would you reply to it?

Mr. BROWN. Yes, we would be glad to get back to you.

Mr. SYNAR. Dr. Trevena and Mr. Brown, my next question is about money. Your testimony states that Nordion was prepared to cover the cost of the irradiations in Omega West as a backup supply.

Now, Mr. Brown, you state in your testimony that at least some of those costs of DOE's backup capacity could be covered through routine irradiations. How much would this add to the cost of Nordion's products and would you pursue that as an option?

Mr. BROWN. Having DOE produce a portion of the moly-99?

Mr. SYNAR. Right.

Mr. BROWN. That is an arrangement we could live with, yes. That would provide the backup that we would be looking for.

Mr. SYNAR. How much would that add to the cost of the product?

Mr. BROWN. I don't know. We haven't gone through that level of detail.

Mr. SYNAR. How much would that add?

Dr. TREVENA. We haven't got there with DOE yet.

Mr. SYNAR. Are you prepared to pursue that option?

Dr. TREVENA. We did start down the road to pursue the option earlier but we got road blocked when it didn't look like there was capacity there, so we didn't get to talk about pricing.

Mr. SYNAR. Are you still prepared to look at it?

Dr. TREVENA. Yes, we are.

Mr. SYNAR. That still leaves us with a single North American processing facility, doesn't it?

Dr. TREVENA. That's correct.

Mr. SYNAR. Let's look at another area. We previously discussed some differences between industry's willingness to invest in accelerators and reactors. The radiopharmaceutical industry has made a substantial investment in accelerators and cyclotrons to produce radiopharmaceuticals. Nonetheless, Dr. Atcher, the Society for Nuclear Medicine and the American College of Nuclear Physicians have campaigned for a new dedicated accelerator to produce medical isotopes, the National Biomedical Tracer Facility [NBTF].

Now, if the industry is willing to make the investments in the accelerators, why do you need this new dedicated facility?

Dr. ATCHER. For two reasons. One is the accelerators that industry has constructed to date have not had the capacity in terms of energy to produce some of the isotopes that would be produced at the NBTF. We're asking for a facility that would be higher in energy and would basically take over the production which is now done at Brookhaven National Laboratory and at Los Alamos using high energy accelerators there.

The other answer to your question is that there are isotopes, which I call "boutique isotopes," for which there is a critical but essential need. They are not commercially viable and don't justify the construction of an isotope producer for commercial purposes. Nonetheless, these radionuclides are necessary for investigators in medical research, as well as fundamental physics and chemistry research.

Mr. SYNAR. Mr. Brown, you both seem to be endorsing in your statements the basic definition of the NBTF worked out in the Purdue workshop, as long as there is a stipulation that it doesn't produce isotopes that are commercially available. Is that correct?

Dr. ATCHER. That's correct.

Mr. BROWN. Yes, that's correct.

Mr. SYNAR. All right.

Although the Department of Energy has said they are basing their October 1993 request for proposals on those definitions, they're requiring interested parties to make a proposal to them that is basically a full cost-recovery proposal. What you all have said in your statements is that that sort of basic research and training is not going to pay for itself and shouldn't be expected to; correct, Dr. Atcher.

Dr. ATCHER. That's correct.

Mr. SYNAR. OK. Industry representatives were asked, according to our study, at a recent National Academy of Sciences meeting about what commitments to the NBTF they would be prepared to make or would envision making.

Mr. Brown, what commitments would the industry make and what isotopes, if any, would you envision your industry buying from the NBTF?

Mr. BROWN. The industry supports NBTF from the research and training perspective. We discussed earlier the fact that the NBTF will produce noncommercial isotopes, isotopes that were not commercially available. So with that charter, we don't anticipate buying any regular production isotopes from NBTF.

Mr. SYNAR. Would the industry insist on proprietary CRADA-type arrangements?

Mr. BROWN. Once again, the isotopes we'd be interested in, we manufacture on our own cyclotrons.

Mr. SYNAR. What about research?

Mr. BROWN. The research——

Mr. SYNAR. Would you support it?

Mr. BROWN. I'm sorry?

Mr. SYNAR. Would you support research, dedicated research projects?

Mr. BROWN. Well, dedicated research projects, if they were focused on a specific radiopharmaceutical, the industry could support it. Broad research initiatives in basic science—with the size of our industry, being such a small industry, we could not support such broad research goals.

Mr. SYNAR. Dr. Trevena, in your testimony, you discuss some of the capabilities of the TRIUMF accelerator facility, which is in Vancouver. Are you suggesting that TRIUMF, as a research facility, could fulfill some of the objectives which are envisioned by the NBTF?

Dr. TREVENA. It is possible, but I would look to the subcommittee that is looking into the NBTF itself to decide whether that and other facilities in North America could provide what NBTF is envisioned to produce. I am not an expert in all the products that might be required. I just suggest it as an option that should be considered.

Mr. SYNAR. Now, Dr. Atcher, I know that your studies have recommended a single, dedicated Federal facility at about $100 million, which is a lot of money. Is there a reason not to examine whether other North American facilities such as TRIUMF and BLIP, the Brookhaven facility being upgraded, that they could either individually or collectively fulfill that isotope production requirement which envisioned for the NBTF?

Dr. ATCHER. There are, and we're encouraging that in terms of the DOE's examination of the problem. However, the facility at Brookhaven, for example, is—I can't remember its age, but it is about 20 or 25 years old. It is coming to the end of its life-span and——

Mr. SYNAR. It is being upgraded?

Dr. ATCHER. It is being upgraded, but it's not going to meet the specifications which the ACNP and SNM panel recommended. The upgrade was rejected by a 2 to 1 vote of the users at the Los Alamos workshop in 1988. Specifically, it doesn't have the beam current, it doesn't have the production capacity, and it is fixed in terms of what can be produced there. Nor was the proposal peer-reviewed by the user community or did DOE consider alternate sites or proposals.

Mr. SYNAR. I'm going to get into that with the DOE this afternoon.

Mr. Brown, what would be wrong with looking at these facilities, as well as Canadian facilities, to fulfill these needs which are identified in the NBTF study?

Mr. BROWN. I think these other facilities should be considered in looking at their production capabilities, yes.

Mr. SYNAR. All right. Now, your testimony suggests, Mr. Brown, that you think that the NBTF or whatever entities devoted to medical isotope research should also address the need for stable isotopes.

Dr. Hahn, you made a similar statement about the need to ensure the supply of stable isotopes for medical research. What do you mean by that?

Dr. HAHN. Well, one is not only in the business of manufacturing the proven products. There are potential uses for new ones continuously being developed in research labs.

A colleague of mine, for example, at Brookhaven, is working on a radioactive isotope of tin that he produces at the BLIP. He needs an enriched tin isotope as the target material, that he told me he has been buying from the DOE Isotope Production Program, on the order of maybe a tenth of a gram per month to do this work. But he's now getting to the stage where he's thinking of moving up into clinical trials.

I asked how much he will need then. He said, if it looks as if it is panning out, that he may have to go to the order of 10 times as much per month. I asked if they have that much in stock? He said, "I haven't asked yet." So his continuing this project will depend on the isotope's continued availability in much larger amounts than he has been using.

There are other situations where one gets a bright idea and wants to try out something to see what the initial properties are. Again, you usually have to have enriched isotopes if you're going to use an accelerator to produce specific radioactive isotopes—for possible medical uses. This is the type of R&D in nuclear medicine that I was alluding to.

Mr. SYNAR. Mr. Brown.

Mr. BROWN. The radiopharmaceutical manufacturers rely on these nonradioactive stable isotopes as target material in our cyclotrons, so the continued supply of this is critical for our industry.

Mr. SYNAR. Dr. Trevena, where does Nordion get their stable supply?

Dr. TREVENA. We buy our stable isotopes from the Soviet Union—former Soviet Union, I am sorry, Russia.

Mr. SYNAR. Now, Dr. Hahn, you and Dr. Atcher both have stated that because of the changes in the way DOE supplies and prices isotopes that you're personally aware of research projects, including clinical trials for medical isotopes, that had been canceled or terminated.

There are some people at DOE who still don't think there is any supply problem here. Bottom line, is there or is there not a supply problem?

Dr. HAHN. Well, there is a particular area of research usually done at nuclear reactors where people have traditionally borrowed isotopes, because the amounts are relatively large—multigram amounts. Here you're talking about loans involving several tens of thousands of dollars per isotope. Formerly, the loan cost would be normal; one would pay carrying charges, plus any reprocessing fees when they returned the material.

The ground rules changed when the isotope production program was restructured a few years ago; the loan fees went up, often significantly. The upshot was that most of the researchers in the country turned in the products they had on loan. They effectively said, "We can no longer afford to keep these isotopes."

Now, you might argue some scientists were hoarding these isotopes, with only vague ideas for future research. That is, if their research plans are important, they would have found the money for the increased loan costs. But I know quite a few people who said to me that they had to make very hard choices; there were several cases where a colleague had a project he/she thought was going to be good, but had to abandon it because he/she just didn't have the money for the needed isotopes.

Mr. SYNAR. Dr. Atcher.

Dr. ATCHER. There are instances in which, again, we have what I call "boutique isotopes," isotopes that you don't need a lot of, less than a gram, but if——

Mr. SYNAR. They are like orphan drugs?

Dr. ATCHER. Yes. And if there is a request for them and Oak Ridge doesn't have those particular isotopes—they're not running their enrichment facilities anymore, so those are just not available.

There have been a couple of instances where we have—in our research program, have wanted to get into developing a new isotope, and the supply of the enriched isotope which we would need to irradiate either in an accelerator or reactor was just not available.

Mr. SYNAR. Dr. Hahn, you gave an example in your testimony where, because of the need for FDA approval, one of Mr. Brown's pharmaceutical companies needed to have some stable isotopes which were to be supplied by DOE; they couldn't use Russian isotopes.

Now, from what I'm reading in your testimony, what you're telling us is that without an approved supplier of stable isotopes, that product just simply wouldn't be marketed. Is that right?

Dr. HAHN. You mean, if they could not get it in the United States?

Mr. SYNAR. Yes.

Dr. HAHN. That's right, that is what my information was.

Mr. SYNAR. OK. And the only other source would be the former Soviet Union and those supplies would not meet the supply requirements of FDA?

Dr. HAHN. Exactly, yes.

Mr. SYNAR. It's clear that the former Soviet facilities are now undercutting DOE in price and have every economic reason to do so. DOE can't compete and, as you mentioned, in the Arthur Andersen study, they recommend either shutting down the DOE operation or deciding that it is in the national interest to maintain the capacity.

Now, in that Arthur Andersen report, they give us an estimate of what it would cost a year, about $1.5 to $2 million. What you seem to be saying, Dr. Hahn, is that from a research perspective, we should probably retain that capacity for that price.

Dr. HAHN. Yes, I would endorse that statement very strongly. The only thing is, if I recall the statement in the Andersen report, they were talking about, I think, operating only one or a few segments of the calutrons. So it would not be a return to full production, but it certainly would be better than what's going on now, which is zero production.

Mr. SYNAR. Dr. Atcher, what's your perspective? Should we retain that capacity?

Dr. ATCHER. I think it is essential to retain that capacity.

Mr. SYNAR. Mr. Brown.

Mr. BROWN. I agree. We feel very strongly that Oak Ridge should start up either the calutrons or utilize newer technology.

Mr. SYNAR. Mr. Brown and Dr. Trevena, how reliable are the supplies from the former Soviet Union? How confident are you that they'll still be available?

Mr. BROWN. So far, the supply has been fairly reliable, but we are a little bit concerned about the instability of the supply.

Dr. TREVENA. We found the supplies to be reliable. We found the quality to be good. We are at present trying to determine whether in fact the product is still being manufactured, or it is being hinted at as perhaps made from inventory. So we are trying to determine that.

Mr. SYNAR. So in the long term you're not concerned, either one of you?

Mr. BROWN. We are concerned with only having the Russians in production, yes. We would like to see production in the United States.

Mr. SYNAR. I understand that your corporation told DOE that it would be willing to pay a premium for a second source, and place orders for stable isotopes in order to get DOE to have that capacity?

Mr. BROWN. My company continued to buy from Oak Ridge for quite awhile after the Russian material was available, yes.

Mr. SYNAR. All right. Are other pharmaceutical, radiopharmaceutical firms, willing to do that or are they more cautious?

Mr. BROWN. I really can't speak for the other companies.

Mr. SYNAR. Dr. Atcher, how important is it that DOE continue to provide stable isotopes?

Dr. ATCHER. It is extremely important, in part because of the points that you covered relative to the stability of supply. In the early days, in which some people were entrepreneuring for the Soviet Union and selling isotopes, enriched stable isotopes, the quality and purity of those isotopes were questionable. But the people who buy—the big customers—the isotopes for which there is a large demand are fairly comfortable with the quality of the material they are getting. I haven't polled the people in the research community about the quality of the materials that they are getting.

Mr. SYNAR. They're going to need it for the NBTF also, aren't they?

Dr. ATCHER. Absolutely.

Mr. SYNAR. Gentlemen, thank you. This has been very helpful as we proceed through this. I may submit some more questions as may other Members. I will ask unanimous consent that additional questions be entered into the hearing record. Thank you all for being with us.

Our next panel this morning will be Greg Friedman, deputy assistant inspector general for audit operations of the Department of Energy, and Mr. Ira Goldstein, Arthur Andersen & Co.

Gentlemen, before you sit down, I think you saw by the last panel that we swear in our witnesses. Does either one of you have any objection to being sworn?

[Witnesses sworn.]

Mr. SYNAR. We welcome you this morning.

And at this time, Mr. Friedman, why don't we have you summarize in about 5 minutes.

STATEMENT OF GREG FRIEDMAN, DEPUTY ASSISTANT INSPECTOR GENERAL FOR AUDIT OPERATIONS, U.S. DEPARTMENT OF ENERGY

Mr. FRIEDMAN. Good morning, Mr. Chairman. My name is Greg Friedman. I am the deputy assistant inspector general for audit operations at the Department of Energy. Mr. Layton, the inspector general, cannot be here today due to illness. He fully intended to participate in these hearings, and he asked that I express his regrets that he cannot be here.

I am here today at your request to testify on audits performed of the Department of Energy's Isotope Production and Distribution Program. The purpose of the Isotope Production and Distribution Program is to produce and sell radioisotopes, and stable isotopes, for a wide variety of research, development, biomedical, and industrial applications.

My office has completed two audits relating to the isotope program. In February 1988, the Office of Inspector General reported on isotope production and related sales at the Oak Ridge National Laboratory in the Mound Plant. On June 30, 1993, we reported on the Isotope Production and Distribution Program's financial statements for fiscal year 1992. Both reports raised doubt as to the viability of the isotope program as it was functioning at the time of our audits.

In our 1988 audit report, we noted that isotope revenue shortfalls due to underpricing of individual products resulted in production disruptions and shortages of isotopes. The audit reported that the Department had not established a uniform pricing policy for the program. For example, the pricing policy at Oak Ridge, the Department's major isotope production facility, did not provide sufficient revenues to cover costs of current isotope production.

The audit also disclosed that the method used to fund the program did not always provide the working capital needed for operating efficiently and maintaining adequate inventories. Furthermore, we noted the Department did not have a central focal point to manage the program.

The Department agreed with the recommendations contained in the audit report, and specifically in a June 29, 1990 policy paper, the Department established a pricing philosophy that applied the full cost-recovery requirement to the total isotope program, rather than to individual isotopes as had been the case. The Department also agreed to seek an annual appropriation for the isotope program with revenues from the sale of isotopes to be used to offset future appropriations. However, we were informed that the Office of Management and Budget subsequently directed that the program seek approval of the Congress for a program revolving fund.

The Isotope Production and Distribution Program revolving fund was created and funded at slightly more than $16 million as part of the Energy and Water Development Appropriations Act of 1990, Public Law 101–101. Finally, the Department agreed to establish a central focal point to manage the program. In June 1992, as has been discussed earlier in this hearing, subsequent to the first Office of Inspector General audit, the U.S. General Accounting Office issued a report which confirmed the problems raised in our audit.

To comply with the Chief Financial Officers Act of 1990, an audit was performed of the financial statements prepared by management for the isotope program for fiscal year 1992. The public accounting firm of KPMG Peat Marwick participated in this audit. The audit report disclosed that for fiscal year 1992 the program had revenues totaling slightly more than $15 million and a net loss of over $7.7 million.

The auditors concluded that the statements prepared by management presented fairly and in all material respects the financial position of the isotope program. However, the audit report identified several material weaknesses related to the viability of the program and problems associated with isotope inventory accounting.

In its first 3 years of existence, as currently formulated, the isotope program sustained cumulative losses totaling $12.5 million. Based on the magnitude of these losses and the need for additional capital as evidenced by the program's decision to borrow $8.5 million from the Treasury in fiscal year 1992 for working capital and for new isotope production capability, and the Department's request for additional borrowing authority of $5 million for fiscal year 1993, there is doubt as to whether the isotope program can remain viable and comply with the program objectives established in Public Law 101–101.

We recommended that the Department restructure the program to place it on a sustainable basis. Management concurred in this recommendation. We have been informed that restructuring options have been developed and that senior departmental officials have been briefed on these options.

The audit also disclosed the Department of Energy contractors managing facilities producing isotopes had never reviewed inventory levels to determine if there were any excess materials, nor had they reconciled inventory records to accounting records. Management, working with the auditors, agreed to a $39.3 million downward adjustment in the value of the isotope inventory.

In summary, Mr. Chairman, problems associated with methods to fund isotope production and sales continue to be of concern. The outcome of the audit of the fiscal year 1992 financial statement raised doubt as to whether the isotope program can successfully carry out its mission, given the constraints under which it is operating. These parallel the findings raised in our 1988 audit report.

This concludes my prepared remarks, Mr. Chairman. I will be pleased to answer any questions you might have.

Mr. SYNAR. Thank you, Mr. Friedman.

[The prepared statement of Mr. Layton follows:]

Statement of John C. Layton

Inspector General

Department of Energy

Before the Subcommittee on Environment, Energy
and Natural Resources

Committee on Government Operations

United States House of Representatives

December 6, 1993

For Release on Delivery
at 10:00 a.m., EST
Monday, December 6, 1993

Mr. Chairman and Members of the Subcommittee, I am here today at your request to testify on audits performed of the Department of Energy's Isotope Production and Distribution Program.

The purpose of the Isotope Production and Distribution Program is to produce and sell radioisotopes and stable isotopes for a wide variety of research, development, biomedical, and industrial applications. My office has completed two audits relating to the Isotope Program. In February 1988, the Office of Inspector General reported on Isotope Production and Related Sales at the Oak Ridge National Laboratory and the Mound Plant (DOE/IG-0251). On June 30, 1993, we reported on the Isotope Production and Distribution Program's Financial Statements for Fiscal Year 1992 (CR-FC-93-03). Although I will describe the specific findings shortly, both reports raised serious doubt as to the viability of the Isotope Program as it was functioning at the time of our audits.

In our 1988 audit report, we noted that isotope revenue shortfalls, due to underpricing of individual products, resulted in production disruptions and shortages of isotopes for important medical, scientific, and industrial applications. The audit reported that the Department had not established a uniform pricing policy or funding mechanism for the Program. For example, the pricing policy used at Oak Ridge, the Department's major isotope production facility, did not provide sufficient revenues to sustain current isotope production. The audit also disclosed that the method used to fund the Program did not always provide the working capital needed for operating efficiently and maintaining adequate inventories. Furthermore, we noted that the Department did not have a central focal point to manage the Program. There were at least four Headquarters and seven field activities involved in the funding and production of isotopes.

We recommended that the Department's full cost recovery concept be applied to the total Isotope Program rather than to the production of individual isotopes, as had been the case. This would allow the Department to take advantage of strong demand for a particular isotope by setting the price at a reasonable amount above cost. The audit report also included recommendations for a revised Program funding mechanism. Specifically, we proposed annual requests for a single appropriation for the Program to fund the level of production for that year with revenues from isotope sales used as offsets to the funds appropriated by the Congress. We also recommended that a central focal point be established to manage the Program.

The Department agreed that isotope pricing practices needed to be reviewed; however, it stated that it was premature to assume that applying the policy of full cost recovery to the total Isotope

Program was the best approach. The Chief Financial Officer subsequently evaluated the Program's financial management, accounting, and product costing practices to develop recommendations to improve the Isotope Program. A June 29, 1990, policy paper established a pricing philosophy that applied the full cost recovery requirement to the total Isotope Program rather than to individual isotopes. Regarding our recommended funding mechanism, the Department agreed to seek an annual appropriation for the Isotope Program with revenues from the sale of isotopes to be used to offset future appropriations. However, we were informed that the Office of Management and Budget (OMB) subsequently directed that the Department seek approval of the Congress for a Program revolving fund instead. The Department also agreed with our recommendation to establish a central focal point to manage the Program and it established the Office of Nuclear Energy as Program manager.

Consistent with the Department's funding strategy, the Isotope Production and Distribution Program revolving fund was created and funded at slightly more than $16 million as part of the Energy and Water Development Appropriations Act of 1990 (Public Law 101-101). The Secretary of Energy was required to set fees in such a manner as to provide full cost recovery, including administrative expenses, depreciation of equipment, accrued leave, and probable losses. Further, Public Law 101-101 included the stipulation that revenues received from the sale of isotopes were to be credited to the revolving fund and be available for carrying out the purpose of the program without further appropriations.

In June 1992, subsequent to the first Office of Inspector General audit, the U.S. General Accounting Office issued a report which confirmed many of the problems reported on in our audit.

According to the General Accounting Office, the Isotope Production and Distribution Program, was experiencing difficulty operating on a self-supporting basis. The General Accounting Office found that the Program: (1) had costs which exceeded revenues because the Program could not control radioisotope production costs; (2) did not have sufficient funding to operate and maintain the equipment used to process stable isotopes; (3) faced competition in the market place; and, (4) lacked capital funds to expand and improve Program operations. The General Accounting Office, however, recognized the Department's efforts to improve operations of the Isotope Program.

To comply with the Chief Financial Officers Act of 1990, an audit was performed of the financial statements prepared by management for the Isotope Program for FY 1992. The public accounting firm of KPMG Peat Marwick participated in this audit. The audit report, issued in June 1993, disclosed that, for FY 1992, the Program had revenues totaling $15,089,822. However, the cost of sales and services totaled $15,870,026 resulting in a gross deficit of $780,204. Further, the Program incurred other expenses of $6,923,880. Thus, the Isotope Program experienced a net loss in FY 1992 of $7,704,084.

The preparation of financial statements is the responsibility of management. They are to be prepared in accordance with accounting principles as required by the Department and OMB. Departmental officials also prepare an overview of the Program, including its history, present status, and anticipated actions which will affect the future status of the Program.
The auditor expresses an opinion on management's financial statements taken as a whole. The audit is performed in accordance with Government Auditing Standards and OMB guidance.

This was the first year that a financial statement audit of this Program was made. The auditors concluded that the statements prepared by management presented fairly, in all material respects, the financial position of the Isotope Program.

The auditor's reports on compliance with laws and regulations and internal controls identified several material weaknesses in the Program relating to the viability of the Program in light of the full cost recovery requirements and problems associated with isotope inventory accounting:

- Public Law 101-101 required prices to be set for isotope sales in such a manner that full cost recovery would be accomplished. During the first three years of this Program, it had sustained cumulative losses from operations totaling $12,589,291. Clearly, the Program has not been able to fully recover its costs. Based on the cumulative operating losses; the need to borrow $8.5 million in FY 1992 for working capital and new isotope production capability; and the need to request additional borrowing authority for $5 million for FY 1993, the audit concluded that there is substantial doubt as to whether the Isotope Program can comply with the Program objectives contained in Public Law 101-101. We recommended that the Department consider restructuring the Program to place it on an efficient and sustainable basis. The Department concurred in this recommendation. We have been informed that restructuring options have been developed and that senior Departmental officials have been briefed on these options. Problems associated with the sale of tritium are illustrative of the difficulties related to satisfying the legal requirement for full cost recovery. The Department's standard cost of the tritium isotope was greater than the market value of tritium. Thus, tritium sales resulted in a net loss to the Program. The audit recommended that the Department perform an economic analysis to determine the best strategy for establishing the standard Departmental cost for tritium and for pricing tritium sales to customers. The Department advised that an action paper would be developed which would address the pricing of tritium.

- The audit disclosed that Department of Energy contractors managing facilities producing isotopes had never reviewed inventory levels to determine if there were any excess materials. Nor had they reconciled inventory records to accounting records. Management,

> working with the auditors, agreed that an inventory adjustment to prior periods representing a $39.3 million decrease in the value of the inventory was necessary. The audit included recommendations that contractors be required to (1) redetermine the allowance for excessive inventory quantities at the end of each fiscal year and (2) perform quarterly reconciliations of the perpetual inventory records and the general ledger accounts. In response to the report, Program management directed all contractors to make appropriate excess quantity determinations in accordance with Department accounting policies and to perform quarterly reconciliations between inventory and accounting records.

In summary, problems associated with methods to fund isotope production and sales continue to be of concern. The audit of the

FY 1992 financial statements raises doubt as to whether the Isotope Program can successfully carry out its mission given the constraints under which it is operating. These parallel the findings raised in our 1988 audit report.

This concludes my prepared remarks. I will be pleased to answer any questions you or your colleagues may have.

Mr. SYNAR. Mr. Goldstein.

STATEMENT OF IRA GOLDSTEIN, PARTNER, ARTHUR ANDERSEN & CO., WASHINGTON, DC

Mr. GOLDSTEIN. Thank you, Mr. Chairman. I am Ira Goldstein. I am a partner with Arthur Andersen & Co., and I am director of the Federal Government practice at the firm. I am pleased to be here to describe for you the results of the March 1993 management study that we provided for the Department.

With your permission, I would like to provide the full report to the subcommittee for insertion.

Mr. SYNAR. By unanimous consent, it will be made part of the record.

[NOTE.—The information is filed for the record in the subcommittee office.]

Mr. GOLDSTEIN. The field work for our review was conducted 1 year ago at the end of calendar year 1992. What we did is examine the Isotope Production and Distribution Program [IPDP] mission and scope, the financial experience that the program had. We analyzed laboratory overhead structures, looked at the world wholesale isotope market, and the program's position in it, assessed their customer relationships including visits and interviews with the key customers, and reviewed the organizational structure and business practices.

With the information that we gathered from these procedures, we developed recommendations that addressed four areas, IPDP's financial status, their market position, cost and profitability, and their business practices.

As other witnesses have pointed out, in 1990, Public Law 101–101 established the isotope revolving fund with a little over $16 million. That was apparently intended to make the program self-sustaining. In the initial 2 fiscal years, however, operating expenditures outpaced cash receipts by $8 million, and the program spent $11 million on process development for new products. As a result, the program used the original appropriation and borrowed an additional $8.5 million from Treasury for new initiatives.

One of our key findings involves the conflict in the program's mission. While the Public Law 101 sets full-cost recovery as a major goal, there are conflicting mandates. The Atomic Energy Act of 1954 encourages the supply of isotopes for research, medical, industrial, agricultural, or other uses with or without charge. We found that these conflicting mandates, one fostering research support and the other focusing on revenue generation, has been a significant confusion point and has been a somewhat conflicting combination; and that has hurt IPDP's business practices and impeded profitability.

In the marketing area, IPDP dominated the stable isotope market largely because of unique facilities at Oak Ridge calutrons. Their 1992 stable isotope sales were about $5.8 million or more than half of the world market of $8 to $10 million. Despite the size of this and its position in the market, this represents a significant decline from the 80 to 90 percent market penetration in 1990 before Russia entered the market aggressively.

The competition that has caused a decline in the program's revenues has been in the stable isotope market, which it previously dominated, from sellers of Russian produced isotopes.

Since 1990, the revolving fund has had negative operating cashflows. These, plus major investments in developing production capabilities, have almost depleted the fund. We concluded that IPDP will have to manage operations aggressively with intensifying international competition in commercial-use isotopes and will have to retain customers and regain former customers to be profitable.

We had three major operational findings. One related to reliable access to production capabilities.

The program shares production facilities with much larger DOE programs, and they frequently alter the production and delivery schedules which affect isotopes. This has affected the program's ability to meet customer needs. They have experienced delays and cost overruns at a majority of the facilities. And most of the facilities are aging and have experienced unplanned shutdowns due to other reasons.

The moly-99 development project that we heard described briefly in the former panel is a project which exemplifies the difficulties that have stemmed from using shared and aging facilities. I can describe more of our review of that program later, if the committee would like.

One issue that summarizes the competitive situation as it relates to the moly-99 situation and the private sector competition involved is that typically there is a window of opportunity for supply, when the world capability is lower than world need; and if a competitor doesn't jump into that supply in what we would call the ability to bring a product to market quickly and economically, generally speaking the window of opportunity for profitability closes.

A second operational area is the excess overhead costs. We identified important impediments to the program's profitability related to overhead costs charged to IPDP by the Department, specifically by laboratory facilities. Much of the existing laboratory overhead would be incurred at DOE even if IPDP didn't exist and would not therefore be directly related to costs incurred by the government because of the program's operation. The current practice of allocating these overhead costs to IPDP distorts the competitive program costs and can lead to poor market positions.

The third operational area is unprofitable excess capacity. At the time of our study, IPDP supported diverse and often underutilized facilities at seven locations to produce isotopes. The strategy maximized the number of production processes available for isotopes nationwide, which is a research motivation quite different from the dictates of a profit-oriented business.

One example of this issue is the calutron operations at Oak Ridge National Laboratory. These were originally built and designed for the Manhattan Project and are currently used to separate stable isotopes. At current market prices, they cannot be operated at a profit. And it appears to us that they cost over $2 million a year simply to maintain the calutrons in ready reserve.

We should point out, in passing, that we do not have a value judgment on whether the calutrons themselves should or should not be operated, but on the expectation that they can be operated profitably.

We had a number of major recommendations and a more lengthy list of operational recommendations. On the major side, the program has had difficulty ranking the competing needs of research and commercial objectives and obviously needs guidance on the desirable balance between the two endeavors in order to continue.

It also needs, in a second area, to reduce and stabilize overhead costs. Most facilities exist to support other much larger government programs and needs. Therefore, their overhead pools are configured from costs which are significantly higher than a profitmaking organization would need or want within a competitive marketplace.

IPDP should consider attempting to negotiate some fixed annual overhead charges for the fixed portion of the incremental overhead. A large portion of the overhead that they are charged is fixed, yet it is allocated to IPDP on a variable cost basis as a percentage of total costs. This way, the program is penalized with added overhead for high volume in a situation in which there isn't significant additional overhead that is actually incurred.

We also have recommendations that relate to reducing the cost for unprofitable capacity and for treating the moly-99 project, which shows the potential of significant profitability if handled correctly, treating that project very cautiously.

Other recommendations exist, and I would be happy to summarize them if the committee would like that.

Mr. SYNAR. We are going to get into those in the questions, so I don't think that is necessary.

Mr. GOLDSTEIN. In summary, we believe that the changes recommended in the report can provide a substantial basis for IPDP profitability if successfully implemented. A major message that we attempted to convey in the report, however, is that if such changes are not made, alternatives to direct operation can be carefully evaluated, such as leasing facilities or creating a quasi-governmental entity. These things have been considered in other places in the international community and, in fact, during our review were suggested to us by some of the competitors.

Mr. Chairman, this concludes my summary of the report, and I would be pleased to answer any questions the committee would like.

[The prepared statement of Mr. Goldstein follows:]

TESTIMONY

Presented to the

COMMITTEE ON GOVERNMENT OPERATIONS

SUBCOMMITTEE ON ENVIRONMENT, ENERGY, AND NATURAL RESOURCES

U.S. HOUSE OF REPRESENTATIVES

on the
Isotope Production and Distribution Program
Management Study, March, 1993

By

Ira Goldstein
Partner
Arthur Andersen & Co.

December 6, 1993

Mr. Chairman and members of the subcommittee:

I am pleased to be here today to discuss our March 1993 Management Study on the Department of Energy's Isotope Production and Distribution Program ("IPDP" or the "Program"). I am Ira Goldstein, a partner with Arthur Andersen & Co. My testimony today will summarize the material compiled and presented for the Department in our report on the management, structure, and operations of the Program. With your permission, we will provide the full report to the Subcommittee for insertion into the record.

INTRODUCTION

The field work for this review was conducted between September 1992 and January 1993. The scope of the study included:

- Examining IPDP's mission, scope, financing, and organization
- Analyzing IPDP's financial experience and status
- Analyzing laboratory overhead structures at selected locations
- Assessing the world wholesale isotope market and IPDP's position in it
- Assessing IPDP's customer relationships; and
- Reviewing the organizational structure and business practices of competitors, as well as comparable private-sector operations, to identify business and financial management practices that could benefit IPDP.

The study included site visits at three of the seven National Laboratories used by the Program for the production of radio and stable isotopes. We conducted telephone interviews with Program personnel at the four laboratories that we did not visit. We canvassed major customers of the Program through personal interviews and used a customer survey to collect perceptions of the Program from a wider range of customers.

With the information gathered through these procedures, we developed recommendations addressing the IPDP's:

- financial experience and status
- market position, including customer perceptions and competitors' practices
- costs, pricing policies and profitability; and
- operating and business practices.

BACKGROUND

Work on the production, separation, and application of isotopes has been underway in U.S. National Research Laboratories since the early days of the Atomic Energy Commission. Many beneficial uses of isotopes have originated from this work; the practice of nuclear medicine is one of numerous notable examples of successful technology transfer from government isotope programs to the private sector. There are now over 36,000 diagnostic procedures conducted each day in the U.S. – as well as 50,000 therapies and close to 100 million laboratory tests each year due to the applications of isotopes in the practice of nuclear medicine. It is estimated that about one out of every three hospital patients in the United States undergoes a nuclear medicine procedure, with a total annual value estimated at $7 billion to $10 billion. The use of isotopes is thus important in innumerable medical, industrial and research and development activities that support continuing improvements in our industrial competitiveness and quality of life.

The National Laboratory complex has been producing and distributing isotopes to support peaceful applications for over forty years. Historically, funding for isotope production came from various U.S. Department of Energy (DOE) programs. In 1990. Public Law 101-101 established the Isotope Production and Distribution Program with a revolving fund of over $16 million apparently intended to make the Program self-sustaining. In the initial two fiscal years, however, operating expenditures outpaced cash receipts by $8 million, and the Program spent $11 million on process development for new products. As a result, the Program used the original appropriation and borrowed an additional $8.5 million from the Treasury to fund new product initiatives.

SUMMARY OF FINDINGS

While Public Law 101-101 sets "full cost recovery" as a major goal, the Atomic Energy Act of 1954 encourages the supply of isotopes for research, medical, industrial agricultural or other uses "with or without charge." The result of the conflicting mandates--one fostering research support, the other focusing on revenue generation--has been a somewhat conflicting combination of missions that has hurt IPDP's business practices and impeded profitability.

The Isotope Program operates in two markets: radioisotopes and stable isotopes. Its 1992 radioisotope sales of $6.2 million were approximately 7 percent of the world radioisotope market. Although research-oriented radioisotopes -- generally not profitable -- represent only 2 percent of the world market for radioisotopes, IPDP generates 15 percent of its sales from that segment. IPDP produces no molybdenum-99 and only very small amounts of cobalt-60. These two products dominate the commercial market.

By contrast, IPDP has dominated the stable isotope market, largely because of unique U.S. facilities such as Oak Ridge National Laboratory's calutrons. IPDP's 1992 stable-isotope sales were about $5.8 million, or more than half of the estimated world market of $8 million to $10 million. Nevertheless, this represents a significant decline from the 80 to 90 percent market penetration in 1990, before Russia entered the market aggressively.

IPDP faces little competition for the radioisotope products that it currently produces. The competition that has caused a decline in the Program's revenues has been in the stable isotope market -- which it previously dominated -- from sellers of Russian-produced stable isotopes.

Since 1990, the revolving fund has had negative operating cash flows. These, plus major investments in developing production capabilities, have almost depleted the fund. With strong and intensifying international competition in commercial-use isotopes, IPDP will have to manage operations aggressively, retaining customers and regaining former customers, to be profitable.

We had three areas of major findings in our report regarding operations challenges. These relate to access to operating facilities, application of overhead costs, and excess capacity. They are discussed below.

Reliable Access to Production Capabilities

IPDP shares its production facilities with much larger DOE programs that frequently alter the production and delivery schedules which affect isotopes. The Program has experienced formidable delays and cost overruns at a majority of the facilities in which it operates due to the competing missions and priorities for the facilities. In addition, many of the facilities are aging and have experienced unplanned shutdowns, resulting in delayed shipments. This is extremely damaging in the highly time-sensitive radioisotope market.

The Molybdenum-99 (Mo-99) development project exemplifies the difficulties that have stemmed from using shared and aging facilities. Mo-99 is an essential isotope in the practice of nuclear medicine in the U.S. It is used to produce technetium-99 (Tc-99) for use in diagnostic studies of the brain, heart, and other organs. Tc-99 is used in more than 70 percent of all nuclear medicine procedures -- over 30,000 procedures per day. Due to Mo-99's short half-life of 66 hours, delivery must be made seven days a week on a reliable basis.

The only U.S. commercial supplier of Mo-99, Cintichem, Inc., shut down operations in April 1990. This left the U.S. nuclear medicine community dependent on a single source of supply for this critical isotope, Nordion, Inc., of Canada.

To provide the U.S. market with a second source of supply for Mo-99 -- and because it can be a highly profitable product -- IPDP chose to develop a production capability for this isotope in the Omega West Reactor at Los Alamos National Laboratory. The Omega West Reactor was primarily funded by DOE Defense Programs, which provided approximately one-third of the operating costs of the reactor. IPDP borrowed $8.5 million from the Treasury in 1992 designated for Mo-99 start-up costs. The initial schedule predicted start of production in early fiscal year 1993.

The Program experienced significant delays in the start-up schedule for Mo-99 production due to a combination of health and safety issues and funding concerns. In addition, the Omega West Reactor is under consideration for permanent shutdown by DOE Defense Programs, and the Mo-99 project appears delayed indefinitely. The initial investment decision made by the Program appears undermined by the absence of reliable support for the reactor in DOE over the long-term and by serious difficulties in establishing production capability. These delays in developing Mo-99 production capability have resulted in revenue shortfalls, increased borrowing from the Treasury, and continued frustration among potential customers. Some potential customers told us that in light of the delays they were establishing their own Mo-99 capability. If this occurs, the "window of opportunity" for profitable supply by IPDP may be permanently lost.

Excess Overhead Costs

A second area in which we identified important impediments to the Program's profitability relates to overhead costs charged to IPDP by the DOE laboratory facilities. Much of the existing laboratory overhead would be incurred at DOE even if IPDP did not exist and is, therefore, not directly related to the Program. The current practice of allocating these overhead costs to IPDP distorts program costs and can lead to poor market decisions.

Since its inception, IPDP has absorbed about $15.5 million in allocated laboratory overhead, or 27 percent of the Isotope Program's total expenditures. Our overhead analysis at the two most significant production sites--Los Alamos and Oak Ridge--revealed that only 22 percent of total overhead charges was incremental. That means that 78 percent of the overhead costs charged to the Isotope Program was not incurred as a consequence of IPDP's presence. Extrapolating these results to the seven production sites shows that, if the costs were more appropriately allocated, IPDP might have shown a $1 million excess in cash flow from operations (3 percent of revenues) rather than an $8 million deficit.

Unprofitable Excess Capacity

At the time of our study, IPDP supported diverse and often underutilized facilities at seven locations to produce isotopes. This strategy maximizes the number of production processes available for isotopes nationwide, a research motivation quite different from the dictates of a profit-oriented business. Five facilities have had a negative cash flow since the revolving fund's inception.

One example of this issue is the continued support of the calutron operations at Oak Ridge National Laboratory. These are electromagnetic separation devices originally built and designed for the Manhattan Project to separate uranium. These facilities are currently used to separate a diverse range of stable isotopes, some of which can only be produced using calutrons. The only other facilities of this design in the world are located in the former Soviet Union. Our analysis indicated that, at current market prices, these facilities cannot be operated at a profit. Continuous operation of one segment of calutrons would require annual supplemental funding of $1.5 million to 2 million to cover operating losses.

RECOMMENDATIONS

Our March 1993 report included recommendations for enhancing operations and profitability. I will highlight our major recommendations here and then summarize the others.

1. Define the Balance Between Profitability and Support of Research

Gradually, IPDP has been defining its vision as a self-sustaining entity. To establish a solid foundation, DOE must clearly define IPDP's mission, specifically as it relates to the production of isotopes for commercial versus research needs. IPDP must clearly communicate this mission to all of its production facilities and gain the buy-in of personnel at the laboratories. Historically, the Program has had difficulty ranking the competing needs of research versus commercial objectives. As I noted earlier, both are supported in legislation and precedent, but guidance on the desirable balance between the two endeavors does not exist.

Commercial-use isotopes should not be produced unless the revenues they generate equal or exceed their incremental costs of production. Our study indicated that, currently, the Program is not generating sufficient profits from commercial-use isotopes to support the loss from production of isotopes for research. If it is determined that the government should support a domestic supply of an isotope that cannot be produced profitably, a government subsidy might be appropriate. At the present time, IPDP supports such products from appropriated operating funds.

If specific isotope products and services are deemed to be of sufficient national value to be produced by DOE with taxpayer support, annual DOE funding combined with such income as can be generated from the sale of products with commercial applications could support continued availability of isotopes for medical, industrial and research applications.

2. Reduce and Stabilize Overhead Costs

Most facilities within which the Isotope Program operates exist to support other, much larger government programs and needs. Many overhead costs reflect the needs of these "host" programs and, in addition, would be incurred and paid for by those host programs in the absence of IPDP. From a pricing standpoint, then, only incremental overhead costs should be allocated to IPDP--those costs that will be actually incurred as a direct result of IPDP's operating at the laboratory.

IPDP should consider negotiating a fixed annual overhead charge for the fixed portion of the incremental overhead charges. A large portion of the overhead charges is fixed, yet all overhead is allocated to IPDP as a variable cost based on a percentage of total costs. To gain the maximum benefit from high-volume production, fixed overhead costs should be charged at a fixed rate. This way, the Program will not be "penalized" with added overhead costs for high-volume orders.

3. Reduce Costs for Unprofitable Capacity

As discussed above, the current strategy maximizes the number of available processes at seven different locations. This is not efficient from a cost vantage point. IPDP should develop a strategy to address its present and future facility needs, targeting unprofitable capacity by either consolidating or closing certain facilities. Unprofitable facilities should be closed or approved for an explicit subsidy.

If the objective is to make IPDP self-financing, we recommend that DOE permanently shut down the calutron facilities, because these facilities cannot break even under current market conditions. On the other hand, if it is determined that it is in the national interest to maintain these unique stable isotope capabilities, separate support must be provided for them.

4. Treat the Molybdenum-99 Project Cautiously

The attempt to produce Mo-99 is the largest, most complex project IPDP has ever undertaken. It represents a significant investment. If successfully brought to market, the new product could be highly profitable and would double the Program's size in five years. If unsuccessful, the project threatens IPDP's very existence.

With this in mind, the government should carefully consider the risks and returns of internal production of Mo-99 versus leasing the facilities to a private-sector enterprise. Generally, the skills required to successfully produce and market Mo-99 reliably and profitably--strict production control from both a cost and delivery perspective--are less prevalent in government organizations than in private enterprises. This makes Mo-99 profitability uncertain, at best, in the DOE environment. Informal offers have been made which could present favorable terms under which the government can realize value for its facilities without current levels of investment risk.

If the government decides to proceed with production, it should institute changes to mitigate risk and enhance the likelihood of positive returns. The first is to assign a dedicated project manager who would focus on ensuring compliance with health and safety regulations and on ensuring adherence to necessary schedule and cost guidelines. The second is to assign a dedicated product manager to develop a comprehensive strategy for marketing the product, concentrating on obtaining and coordinating customer commitments to buy Mo-99 as soon as possible.

5. Other Recommendations

Other recommendations communicated in our report regarding the business practices of IPDP included the following.

> **Price to Market** - To compete in the isotope markets, IPDP should set prices to market levels. IPDP's current practice is to set prices principally based on the full cost of production for each product. As a result, some products are overpriced relative to demand and others underpriced.

Strengthen Marketing - Largely because of the laboratories' historic research orientation, IPDP has insufficient procedures to know and serve its market. Supporting research and recovering costs have assumed greater importance in the Program than meeting customer needs. We recommend that the IPDP remove marketing responsibility from the laboratories and coordinate staff and activities under common control.

Improve Delivery Reliability - The most important success factor in the radioisotope market is reliable delivery, because these isotopes often have half-lives measured in hours. Reliable delivery should be the IPDP's top priority for radioisotopes. The conflict with other programs' priorities at shared facilities hinders this, so IPDP should negotiate a lease agreement for its share. This would provide cost stability, as well as a commitment for IPDP irradiation time and production scheduling at the laboratories.

Establish Accountability to IPDP - Since accountability is a key element of effective management, IPDP should designate a full-time manager for each major project, allow that person to report independently of the laboratory, and link the manager's evaluation and compensation to the project's success. A product manager, responsible for marketing and operational activities, should be assigned to significant isotopes. This person would be responsible for product profitability and evaluated by IPDP management.

Manage Profitability, Not Cost - IPDP should abandon its current cost-center model in favor of profit centers, whose managers would be evaluated on profitability, not spending within authorized limits. At a minimum, profit centers should be set up at the laboratory level. Facility-level profit centers within the laboratories would improve management even more by focusing more closely on specific cost drivers.

Establish Business-Oriented Financial Reporting - Recording transactions on an accrual, rather than a cash, basis will provide accurate earnings and balance sheet information. Matching costs with revenues will improve analysis and decision making based on true operating results. Production costs should be fully allocated to the primary products. Secondary products, or byproducts, should be allocated only the incremental costs of their production. Those byproducts produced in vast quantities and whose sale is not expected to be realized for many years should not be allocated production costs.

Enhance Product and Project Costing - We recommend that IPDP adopt a product and project cost accounting system that reports actual costs based on activities that drive the costs. Knowledge of true product and project cost is essential to monitor and control operations effectively.

Realign Positions to Enhance Capabilities - Central control of operations underlies many of our recommendations. Thus it is logical to create a headquarters marketing manager and an operations manager (with product and project managers in key areas). As noted earlier, a business perspective and business skills--not a research orientation--will serve to keep profit-making initiatives on track. This must not be another layer of bureaucracy but a reallocation of human resources from marketing and sales in the field. Moreover, the individuals need not work at headquarters; Managerial, not necessarily geographic, centralization is the objective.

6. Overall Program Viability

IPDP's success hinges on meeting two criteria: reliable delivery of radioisotopes and competitive prices for stable isotopes. Presently, neither standard is being met. To rectify this situation, four crucial conditions must be met.

- The program must have access to reliable operating and production facilities.
- There must be reasonable and predictable operating costs at these facilities, which include only direct costs of production and distribution and incremental overhead costs.
- There should be a reduction in unprofitable facility capacity.
- Separate funding should be provided for research-oriented isotopes.

These success factors require significant DOE commitment if IPDP is to budget and schedule production effectively and recover its costs. However, implementing the set of changes necessary to accomplish this will not be easy in the DOE/government environment. Yet, without meaningful changes in these areas, IPDP's competitive viability is questionable.

For these reasons, we have recommended that, as DOE considers the operational and competitive challenges for IPDP, it also consider alternatives to the present "owner/operator" status. Leasing its production facilities to private enterprise has been specifically proposed, as well as other frameworks. These generally offer future cash flow while transferring production and delivery risks to others. Other government isotope enterprises - - e.g., Great Britain and Canada - - have successfully evolved in this direction.

SUMMARY

Operating profitability within a government environment is difficult even under the best of circumstances. In its secondary position at most facilities, IPDP's challenge is formidable. DOE and IPDP must address the question of whether the changes essential to ensure sustained viability of the Program can be successfully implemented within the present DOE and Government environment. We believe that the changes recommended in our report will provide a substantial basis for IPDP profitability if successfully implemented. However, if such changes are not supported, alternatives to DOE operation should be carefully evaluated. Other possibilities for the use of unique government facilities for production of isotopes, such as leasing facilities or creating a quasi-government entity, should be carefully considered. Under present operating conditions, organizational framework and production policies and procedures, financial success appears problematic at best.

Mr. Chairman, this concludes my prepared testimony. I would be pleased to respond to any question you or Members of the Subcommittee may have.

Mr. SYNAR. Thank you, Mr. Goldstein. I would like to ask unanimous consent that the inspector general's audit be part of the record, too.

[NOTE.—The information is filed for the record in the subcommittee office.]

Mr. SYNAR. Mr. Friedman, let me start with you. You recommended that a single program office be created to manage the activities of the Departments isotope distribution program.

Mr. FRIEDMAN. That is correct, sir.

Mr. SYNAR. And you proposed that the activities be funded out of a single no-year appropriation with provision for offsetting revenues.

Now, what is different about that structure you proposed in 1988 and the one that's in place today?

Mr. FRIEDMAN. We did not recommend, Mr. Chairman, that a revolving fund be established encompassing a self-sustaining aura to the program. We envisioned that there would likely be a need for additional appropriations in subsequent years.

Mr. SYNAR. So the primary thing is that you always envisioned continuing appropriations to ensure stability, but you intended the program to be a cost-recovery program. But as you know, it still isn't recovering its costs now.

Mr. FRIEDMAN. Yes, sir, that's correct.

Mr. SYNAR. All right. How would the financial picture be different today if we had adopted the original proposal?

Mr. FRIEDMAN. Well, on the assumption that the program had been well managed over time and that some of the issues that are raised in our 1993 report dealing with overhead allocation, inventories, and those sorts of things had been treated, and if there had been a recognition of the need for continuing appropriations, we feel the program would be sustainable as it currently functions.

Mr. SYNAR. Your office also recently completed a Chief Financial Officers Act audit of the DOE isotope program, and I realize that it is a financial audit, not a program review. But based on that work that you have done, it's clear that the revolving fund has not produced the stable financial base that you envisioned in 1988, has it?

Mr. FRIEDMAN. That's quite clear.

Mr. SYNAR. In fact, according to that audit, during the first 3 years of operation, the program sustained cumulative losses of $12.5 million?

Mr. FRIEDMAN. That's correct, Mr. Chairman.

Mr. SYNAR. Is there a private company, Mr. Goldstein, that would be able to operate or would they be bankrupt under that scenario?

Mr. GOLDSTEIN. I think obviously over a period of time you have to either turn a profit or stop producing.

Mr. SYNAR. All right. Now, Mr. Goldstein, at the beginning of your report you outline the contradictions between the Department of Energy's longstanding missions. On the one hand, under the Atomic Energy Act, DOE must provide isotopes at a reasonable cost while encouraging research and development. On the other hand, we now have Public Law 101–101 requiring the program to recover full costs.

You basically seem to conclude that support for research is simply not going to pay its way and that the Department of Energy needs to either separate its support of research activities from those activities for which it can recover its costs. Is that a pretty good summary?

Mr. GOLDSTEIN. Yes, that is, sir.

Mr. SYNAR. OK. Now, in your testimony you state that government subsidies for research isotopes might be appropriate, correct?

Mr. GOLDSTEIN. Yes.

Mr. SYNAR. In practice, there also is a second conflict, isn't there, in the fact that the Department of Energy is not supposed to compete with private industry?

Mr. GOLDSTEIN. It has been a difficulty that's challenged this program from the beginning and creates a separate competitive dilemma.

If you put the Department in a position where it cannot compete with industry, you put it in a position where it will then start product production at a point at which nobody else is producing it, establish its profitability, and then be required to stop producing at a point at which somebody in industry concludes they can make profit. No bank would loan you funds under a situation—development situation like that, so it certainly is a second——

Mr. SYNAR. So what we have done, we have told DOE to go out and make enough money to cover all its costs, even at the expense of research activity, and by the way, you're not supposed to compete with those markets. They really have very little chance of succeeding under that scenario, don't they?

Mr. GOLDSTEIN. I would say that's true.

Mr. SYNAR. Is Omega West at that stage?

Mr. GOLDSTEIN. I think the problems that have created difficulty for Omega West are more related to the difficulty in bringing the facility into some production capability quickly. The financial analysis that is based on the program's numbers indicates to us that with proper productionizing, there is a potential profitable market there for Omega West. I'm not sure, as the industry said this morning, that the industry would come into competition with a moly-99 production which required a high-powered reactor.

Mr. SYNAR. Now, you also conclude that notwithstanding the intent of Public Law 101–101, that the DOE just simply can't operate the program. Is that correct, aside from the need to make a profit?

Mr. GOLDSTEIN. I'm sorry. Are you asking, if 101 were not in existence, would there still be a problem in terms of operating?

Mr. SYNAR. Yes, because of the way DOE operates the program.

Mr. GOLDSTEIN. Well, I think that the laboratories in which DOE is making these production choices are laboratories which are staffed by people who are oriented toward research and not toward production; and since one of the primary success factors in this market is reliability of delivery, it is almost impossible to provide that kind of reliability in a situation in which research factors change the schedule and change the production all the time.

Mr. SYNAR. All right. I want to look at one of the examples, if we could. Let's raise the issues one at a time.

You point out that there are a number of sites which are receiving funding from the isotope program, but which are not really producing a product or a profit and in the business world would be all but shut down. Now, for example, the calutrons at Oak Ridge, is that a good example of that?

Mr. GOLDSTEIN. Calutrons are not operating at this point, yes—at least were not at the point at which we completed our study.

Mr. SYNAR. There is no way Oak Ridge could compete with the Russians, right?

Mr. GOLDSTEIN. Well, the Russians were setting their prices by taking the DOE list, cutting the prices by about 40 percent, and selling at list as defined by the Energy Department minus some percentage. So they certainly could not compete that way.

Mr. SYNAR. And that's likely to continue. They have learned this capitalistic routine well, haven't they? They have learned how to keep competition down. It's amazing, isn't it? We have a situation over there which all of us are aware of: that is there is political instability. We've also heard that there is at least one major industrial customer willing to pay a premium to keep DOE in business. If commercial customers think that maintaining U.S. capacity is important, shouldn't DOE think it's important?

Mr. GOLDSTEIN. Well, I had every indication during this review that the Department of Energy did think it was important.

Mr. SYNAR. They did think it was important?

Mr. GOLDSTEIN. That was the indication that we had. They contracted with us, specifically targeted to identifying ways to become more competitive and to overcome the cost problem.

Mr. SYNAR. If that is the case, why hasn't DOE systematically decided to fund some of these activities and facilities?

Mr. GOLDSTEIN. I can't answer that from my perspective.

Mr. SYNAR. We will ask them later. You would concede, wouldn't you, Mr. Goldstein, that because of this full cost-recovery requirement that DOE has that doing things like selling off the research material collections at Oak Ridge might not be such good national policy?

Mr. GOLDSTEIN. Well, again, we just are not in a position to make recommendations that relate to what the national need would be. We tried carefully to say in the report that——

Mr. SYNAR. But they're selling off assets because of the full cost recovery requirement.

Mr. GOLDSTEIN. I am aware that they are selling inventory, and that they were while we were doing our work; and we did not identify anything commercially inconsistent with that. But I was not aware of selling, selling off public capability.

Mr. SYNAR. I guess what I am trying to say is that full cost recovery may not necessarily be good national policy.

Mr. GOLDSTEIN. From a market standpoint and from a research standpoint, it certainly undermines those objectives.

Mr. SYNAR. Now, you raise another issue concerning DOE's approach to managing the isotope program and you say that the way in which DOE's facilities and contractors charge the isotope program both direct and indirect costs shows that because DOE imposes overhead charges on the program, as if it were an appropriated funds program function, that it's absorbed millions of dollars, literally, in additional costs.

Now, according to your testimony, DOE's program would be about $1 million in the black—instead of the millions of dollars in the red that it is—if DOE had changed the way indirect costs were assessed. What is going on here?

Mr. GOLDSTEIN. I think there is a great deal of misunderstanding about what is going on here. And if I could take one moment to explain it by analogy, I think it would be helpful.

The facilities within which the program operates were created and are supported for research purposes and those are much more expensive to support than a commercial activity would generally be. The Department incurs many billions of dollars for those facilities. When it charges a small commercial operation even its fair share of those full costs, the commercial operation ends up paying a significant—a proportional share of, what can we say, a Cadillac overhead cost, when in fact if we had created that for commercial purposes, a small Honda would do just fine.

So even where—and I think the gentleman from Nordion used the term "fair"—even where the proportion of the overhead pool is fair to the Department, the size of the pool is configured in order to support research capabilities in the laboratory, and not the way we would set it up if we were going to try to do something from a commercial standpoint.

The second part of it has to do with pricing and decisions based on pricing. I make my pricing decisions based on incremental costs and not on full cost, because I am only required to cover the incremental expense from the production. The Department, under cost allocation standards, allocates full costs. And as a result of that, it leads the program to look as if they would not be profitable from selling some isotopes, when in fact they would be because the incremental difference would be smaller than the full cost difference.

Mr. SYNAR. All right.

Mr. Friedman, back to you. You site another example on the way DOE's financial practices penalize the isotope program. This one's related to tritium sales. According to your audit, the Department of Energy was charging the isotope program more than the market value of the isotopes. In fact, the program lost over a quarter of a million dollars during 1992 on those sales.

Now, what is the story here?

Mr. FRIEDMAN. Well, Mr. Chairman, it really is pretty much as it seems on the surface. Essentially, the transfer cost, which is the cost basis that the Department uses for the isotope, the tritium that was sold, was pegged by the Department at a little over $1 million in fiscal year 1992. Sales revenues equaled about $790,000 during that same period, resulting in a loss of a little over a quarter of a million dollars, as you stated.

Mr. SYNAR. Why is DOE charging more than the market?

Mr. FRIEDMAN. Well, it's not that DOE is charging more than the market. It's just that the overhead concept and the other factors that go into the charges that——

Mr. SYNAR. But they're charging themselves more, are they not?

Mr. FRIEDMAN. I am sorry?

Mr. SYNAR. Than the market?

Mr. FRIEDMAN. Yes.

Mr. SYNAR. They're charging themselves more than the market?

Mr. FRIEDMAN. Well, the tritium is produced in essence within the Office of Defense Programs. The Office of the Chief Financial Officer sets a transfer amount, which is essentially the cost basis for that product.

Mr. SYNAR. But isn't it more than the market?

Mr. FRIEDMAN. It is, yes, absolutely.

Mr. SYNAR. That's interesting. When you require the stable isotopes to be sold at market, why wouldn't that apply to tritium?

Mr. FRIEDMAN. I can't answer that, Mr. Chairman. I really don't know the answer.

If I can add, at one point Mr. Goldstein alluded to the generic problem of overhead allocation in the Department of Energy as it applies to these sorts of programs. And this is a perfect example of the problems that arise.

Mr. SYNAR. That's what I was about to ask you. DOE charges the isotope program for direct costs for its use of the production facilities based upon the number of users rather than the program's actual use.

Now, if in any given year the isotope program turns out to be the only user of a hot cell or some other facility, they pay 100 percent of the operating cost of the facility even though they only use it for a month, correct?

Mr. FRIEDMAN. That is my understanding, yes, sir.

Mr. SYNAR. Is that correct, Mr. Goldstein.

Mr. GOLDSTEIN. Yes, and I think that is the situation confronting them at Omega West right now.

Mr. SYNAR. What effect does that have on the whole accounting?

Mr. GOLDSTEIN. Well, for one thing, it makes it impossible to predict in advance whether you can produce something at a profit, unless you know whether every other user will be using it.

Mr. SYNAR. All right.

Now, Mr. Friedman and Mr. Goldstein, one of the issues raised in your reports is related to the internal DOE structure, that DOE often, very candidly, is not a reliable supplier in the market, which as you heard from the first panel demands reliability. This is especially true for reactor-produced radioisotopes.

Mr. Friedman, your report cites problems with the delivery of irridium and cobalt-60. Mr. Goldstein, your report cites problems with irridium. Why is the DOE unable to be a reliable supplier?

Mr. FRIEDMAN. Well, Mr. Chairman, I want to point out that our report, the portion of the report dealing with irridium and cobalt-60, pertains primarily to supplemental information that was provided by management as part of the financial statement. But I think, based on the work that we have done to date and based on our observations, there are several factors, and I think they have been discussed to a degree today—aging facilities, equipment shutdowns, safety concerns and changes in operating methods and equipment. And the cumulative effect is, I think, to make DOE an unreliable supplier in several instances.

Mr. SYNAR. Mr. Goldstein.

Mr. GOLDSTEIN. I would say there are three primary reasons. One is the decentralized nature of the responsibility for delivery, which is accepted and the responsibility of the research laboratory. Second is the culture of the entire facility and program based upon research priorities. And the third is the timeframe of problem resolution.

When there is a leak at a reactor in a private sector facility, as Nordion described before, you do everything you can to overcome the strike. When there is a leak at a reactor in a Federal Government facility, it becomes a long term, protracted attempt to resolve it. And that's very difficult.

Mr. SYNAR. We will get into that this afternoon.

On the management side, Mr. Goldstein, you point out something that's really fascinating to us. You point out that DOE doesn't really even have a marketing arm or a long-term marketing strategy. In fact, what we have come up with is this scenario: The DOE is supposedly trying to market these products so it can stay in business, but it doesn't really have any salesmen. Isn't that right?

Mr. GOLDSTEIN. The individual laboratories have people who are order takers, and I think——

Mr. SYNAR. They're not a marketing operation, are they?

Mr. GOLDSTEIN. They in some cases carry the title marketing, but by and large what we found is, they take orders. Now the direct—I should——

Mr. SYNAR. Who does the marketing?

Mr. GOLDSTEIN. Well, I should add, thank you for asking that question, the director of the program during the period of time that we did our review, spent pretty much his full time marketing the product.

Mr. SYNAR. That is not his job really, is it?

Mr. GOLDSTEIN. Well, we would generally perceive a chief executive officer as being broader than that.

Mr. SYNAR. You know, it might be interesting to ask Dr. Trevena how many marketing people he has out there pushing it; but that will be one of the questions we ask for the record.

Now, you also suggest, Mr. Goldstein, that DOE really hasn't put in place a product development strategy or a financial business plan that reflects the fact that they're supposed to be self-supporting. Why not?

Mr. GOLDSTEIN. Well, I believe that the period of time since Public Law 101 was passed has largely been spent putting out fires and attempting, from an executive standpoint, to market sufficient production to stay afloat for another 3 months or 6 months. I don't think there are the resources at a program level to do the kind of strategic and financial planning that would be necessary.

Mr. SYNAR. They don't have a lot of business-oriented people running around there, do they?

Mr. GOLDSTEIN. Well, the program is staffed by the people who have been running the isotope program for many years, and——

Mr. SYNAR. What kind of management do you need?

Mr. GOLDSTEIN. I should say that I spent 17 years in the Federal Government. So I would not be the right person to be critical of the ability of a Federal Government staff to do profitmaking enterprise. Nor, for that matter, would Arthur Andersen be in a position to say that.

However, it is a different set of strengths. And my experience at the laboratories we visited and at the program taken as a whole is that the staffing of this particular program is very heavily oriented toward the importance of retaining national research needs and what you, I think, appropriately called "orphan isotopes." And those are functions that seem quite valid from a research standpoint but don't contribute to profitability.

Mr. SYNAR. Your report goes on that DOE has had a number of problems with product development. In particular you cite problems with medical isotope production at Los Alamos, irridium production at Oak Ridge, cesium at Hanford, and calcium at Mound.

Mr. Friedman, your audit cites high development costs in these isotopes. Now we're talking about significant cost overruns or, in some cases, outright losses. What is the problem here? Are we just—are we bad managers or is this a symptom of the aging facilities, or both?

Mr. FRIEDMAN. Well, as the audit of the fiscal year 1992 financial statement audit showed, Mr. Chairman, the Department has spent about $11.6 million in the 3-year period for process development startup costs, which we think is obviously very sizable. I don't think we have enough information to give you a definitive answer. But I think there are enough questionable decisions that have been made that one would have to doubt as to whether the program has been entirely well managed.

Mr. SYNAR. Mr. Goldstein.

Mr. GOLDSTEIN. I think that during our review we spoke with a number of other suppliers, all of whom indicated that as they shifted to profitmaking capability, they made major organizational and major personnel changes.

In addition, the capitalization of the program in the beginning I think was not created with an eye toward what type of investment would be necessary to take these aging facilities and make them reliable in a product—in a profitmaking venture. And I think those contribute to the problems they are having.

Mr. SYNAR. The staff is telling me that the program really doesn't control the facilities, do they?

Mr. GOLDSTEIN. No, they do not.

Mr. SYNAR. So even if they wanted to make the changes, they would not be able to?

Mr. GOLDSTEIN. If they were capable of putting the funding on the table, the facilities are all too happy to make what changes need to be made.

Mr. SYNAR. I have noticed that with money.

Mr. GOLDSTEIN. Yes. I should also say, though, that the host capability in each facility would have ultimate veto authority over that. So, for example, since Omega West is a defense facility, that the changes would be done only with the approval of the defense programs organization, and comparable in Mound and some of the other places.

Mr. SYNAR. On that Omega West medical isotope project, if I read your report correctly, it looks like the project's ability to pay for itself was marginal even as originally conceived. Is that a pretty fair reading?

Mr. GOLDSTEIN. It depended heavily on market share and price, and we would have questioned it further, but for the fact that all of the major suppliers indicated quite clearly that they were prepared to make commitments for significant production capabilities at significant prices if Omega West were to come into production. And that did give us the sense that this was potentially a significant profitmaking venture if it could be brought to market timely.

Mr. SYNAR. Well, you ran some sensitivity cases on what you thought would happen to the economics of the project if there was a 6-month delay or if DOE's defense programs no longer needed the reactor and dropped their financial support.

Now, the truth is, isn't it, Mr. Goldstein, that DOE's defense programs have dropped their support, and there are going to be substantial delays, and there are going to be added capital costs to repair, start, and upgrade that reactor. The additional capital expenditures are now estimated to be on the order of $10 to $11 million. In your view, what do these events mean for the economics of the project?

Mr. GOLDSTEIN. Well, I think when coupled with the fact that other suppliers are bringing production capability to the market, it requires that there be some zero-base assessment at this point of the impact of the delay and of the costs at defense.

Mr. SYNAR. Now, you're not making a policy judgment on whether they should have that capacity; you're making an economic judgment, right?

Mr. GOLDSTEIN. Our report was based on the finances and economics, not on policy.

Mr. SYNAR. Now, another issue raised in your study, Mr. Goldstein, that we discussed in our 1992 hearing with GAO, is the fact that the revolving fund was undercapitalized. In other words, the Congress didn't give the program enough startup capital to cover its investments and the costs that it would incur. Your own review found no evidence that before Congress established that revolving fund there was any detailed financial analysis of the program or its future capital needs, right?

Mr. GOLDSTEIN. That's correct.

Mr. SYNAR. In fact, Mr. Friedman, according to your audit, the program was "overvalued" in the sense that it has considered its isotope inventories to be worth far more than they really are in the market; not necessarily what they were worth to the research community, but they are worth if they were treated as a business inventory.

Now, as a result of that audit, DOE had to reduce the value of its inventory by more than $38 million, did it not?

Mr. FRIEDMAN. That's correct.

Mr. SYNAR. Now, Mr. Friedman, would you please explain why that was necessary?

Mr. FRIEDMAN. Well, Mr. Chairman, as we began the audit, we entered into a number of discussions with the contractor program managers, as well as the DOE program managers. We determined that since the initiation of the program, nobody had really taken a careful look at the valuation of the assets, as to whether there were in fact excess materials in the inventory.

After a number of discussions, management suggested a 5-year window, that is to consider excess all quantities which exceeded the demand for the prior 5-year period, which seemed to us to be a reasonable point of view. That formula was applied at all the locations. On that basis, the $38 million write-down took place.

Mr. SYNAR. Now, gentlemen, according to the audit we have been talking about, Mr. Friedman's audit, DOE received authorization to borrow $8.5 million from the Treasury in fiscal year 1992, another $5 million in fiscal year 1993. This year, the DOE requested and received a straight appropriation of about $3.9 million. But there is no indication that these funds will be enough to keep the program financially solvent, is there?

Mr. FRIEDMAN. We don't see that as a possibility, Mr. Chairman.

Mr. SYNAR. Mr. Goldstein.

Mr. GOLDSTEIN. It's difficult for me to comment on that. Our review ended a year ago.

Mr. SYNAR. It appears that the program was initially undercapitalized, but it sounds like they've been doing a lot of refinancing since then. What is the problem here?

Mr. GOLDSTEIN. The program, as all government programs, is on a cash basis. The program looks for additional financing when it becomes cash poor. There is a negative—significant negative cashflow from operations, and periodically one would expect you to have to come back to the well.

Mr. SYNAR. Is this a management problem, is that what you're saying?

Mr. GOLDSTEIN. I would have to say it's a combination of the absence of any forward looking financial plan that establishes how much you need to finance and how you will spend it, looking forward from a moment in time; and the financial realities of competing in this marketplace, given the costs that the program is having to carry is like a 500-pound chain around its leg.

Mr. SYNAR. So that full cost-recovery requirement is killing us?

Mr. GOLDSTEIN. Very difficult to recover in this marketplace.

Mr. SYNAR. Now, every year we figure that the isotope program is paying hundreds of thousands of dollars in interest on borrowed money; is that right, Mr. Friedman.

Mr. FRIEDMAN. Yes, in fiscal year 1992, Mr. Chairman, it was nearly $308,000. And obviously, as the amount of borrowing increases, the amount per year will increase.

Mr. SYNAR. And the fact that DOE is requesting direct appropriations is recognition that the program is not financially self-supporting; isn't it, gentlemen?

Mr. FRIEDMAN. I believe that is the case.

Mr. SYNAR. Mr. Goldstein, you make a number of very insightful observations and recommendations. The bottom line is that, notwithstanding the Department of Energy's problems such as the aging facilities that Mr. Friedman talked about, the program could be viable if DOE changed the way it was doing business.

For example, if the program did not spend millions of dollars on unproductive new products, and if DOE changed its system for charging for the use of the production facilities and overhead, and if DOE changed the way it prices tritium, and if the program adopted some of your recommendations about marketing, financial planning, and management, many of these problems could be fixed, couldn't they?

Mr. GOLDSTEIN. Yes, I believe so.

Mr. SYNAR. Along these lines, Mr. Friedman, your audit included a general recommendation that DOE restructure the whole isotope program to place it on an "efficient and sustainable basis." Now what are the specific recommendations you make?

Mr. FRIEDMAN. Well, that is the recommendation we made, Mr. Chairman, and we did not lay out a specific plan for how the program is to be restructured. But based on the work that we have done to date, it seems to me that there are a number of basic policy issues which need to be resolved before anyone can lay out a logical game plan for the future for this program.

Mr. SYNAR. What were those considerations?

Mr. FRIEDMAN. Such as, should the Department of Energy be the supplier of last resort for the isotope needs of domestic users in the United States? To what extent should the taxpayers be asked to support the program? Is it acceptable for industrial users, medical research users in this country to rely upon a single source of supply for needed isotopes—in fact, a foreign source of supply?

So there are a number of issues which need to be resolved before I think any logical game plan can be derived; some of them have national policy implications.

Mr. SYNAR. Gentlemen, thank you both. I think both of the reports have been, as with the first panel, very helpful to the investigation.

Because of scheduling, we're going to have to break at this point. We will recess until 1:15. At that time, we will have Bill White with us. I apologize for this, but in order to get the Deputy Secretary, we had to make this break.

So we will be recessed for about 1 hour and 15 minutes.

[Recess taken.]

Mr. SYNAR. Subcommittee will come back to order.

For our final panel today we are glad to welcome for his first appearance before the subcommittee, Mr. William White, Deputy Secretary, and he is accompanied today by Mr. E.C. Brolin, Mr. Owen Lowe, Dr. Patrinos, and Dr. Knuth. Welcome.

Gentlemen, it is the policy of this subcommittee in order not to prejudice past or future witnesses to swear in all our witnesses. Do any of you have any objection to being sworn? Please rise and raise your right hand.

[Witnesses sworn.]

Mr. SYNAR. Mr. White, welcome. We will include not only your entire testimony, but everything else you have sent us, and we look forward to your summarizing here in about 5 minutes.

STATEMENT OF WILLIAM WHITE, DEPUTY SECRETARY, U.S. DEPARTMENT OF ENERGY, WASHINGTON, DC, ACCOMPANIED BY E.C. BROLIN, ACTING DEPUTY DIRECTOR, OFFICE OF NUCLEAR ENERGY; OWEN W. LOWE, DIRECTOR, OFFICE OF ISOTOPE PRODUCTION AND DISTRIBUTION, OFFICE OF NUCLEAR ENERGY; DR. ARI PATRINOS, ACTING ASSOCIATE DIRECTOR, OFFICE OF HEALTH AND ENVIRONMENTAL RESEARCH; AND DR. DONALD F. KNUTH, DEPUTY ASSISTANT SECRETARY FOR FACILITIES, OFFICE OF DEFENSE PROGRAMS

Mr. WHITE. OK. Thank you for inviting me. I want to do three things in this 5 minutes. First, communicate to you the priority that I see to be given to this isotope program. Second, to share with you my impressions of what some of the essential problems have been in this program. Third, to tell you what the Secretary of Energy and I think may be some constructive solutions to those problems.

The priority of the program. I believe that the humanitarian impact of isotope production is one of the very great and significant contributions that the research efforts within the DOE has been able to produce in the past. In a way, they are a classic case of how technologies that were developed originally for other uses, specifically military uses, have been effectively transferred to beneficial research and medical uses in the nondefense economy. So to answer the big question about whether this program as a whole is a priority, I believe the answer is definitely, yes.

There are some trends, though, that are bad for this program and have resulted in some dilemmas that the program faces that you and your committee here have been very helpful in highlighting, I might add, as well as various reports in the past.

Let me name five of those trends, and identify them as I see them in my words, that have gotten the program in the situation that it is now.

First, the facilities are aging and that means that, instead of simply operating expenditures, you are talking about capital expenditures, in many cases which will have to be made so that production can continue in a manner that is compatible with the environmental safety and health concerns.

Second, the revolving fund concept appears to me at least to have had a fatal flaw that it did not account for the public interest, which may necessitate production of some isotopes, even if we were not able to recover their cost. This is true of some of the medical isotopes and research isotopes as well. Even though I would agree with the reports of the inspector general and Arthur Andersen Co. and have emphasized again to our own people that we should try to maximize the revenues in the program.

Third, the policy of no competition with private enterprises capable of making these isotopes is, in a way, as you think about it, and I think you have identified it in the past, somewhat in conflict with the idea that the program has to be self-sustaining and profitable, again, showing some of the flaw in the revolving fund concept.

Fourth, there has been a declining mission for the reactors in other programs, such as the defense programs. We all know what has happened to both civilian and defense reactor use.

Finally, the program has been housed in the Energy Department, which is a very talented Department, which members of this committee know encompasses far more than just what is traditionally considered energy. But we are not the department of basic medical research or public health or pharmaceuticals or medicine. So there need to be very important constituencies that are brought to the table in making decisions concerning the priority of this program, which in the normal budgetary process of the Department of Energy as such, that type of expertise is not always at the table.

Solutions, and I am not pretending that these are the only solutions, but I want to hit some of the big ones. First, the Secretary and I are committed to making some appropriate capital expenditures, including the capital expenditures required for the Omega

West reactor. We have directed a reprogramming and budgeting request for fiscal year 1995 to make that happen. Second, to the extent that it is necessary to seek appropriations, we intend to do so because of the flaw in the revolving concept, which I identified.

Third, we need to emphasize and reemphasize to the people working in this program, as I have and my testimony today does, the priority given this program within the nuclear reactor research portfolio of our Department.

Fourth, we have made changes in management and continue to make some changes, so that we have people who have ownership and responsibility for both production that we have now and marketing.

Fifth, we intend to implement the Arthur Andersen recommendations, some of which have been implemented so far, some of which shall be implemented later. There are others which may not be implemented, because they are based on the assumption that you are going to use a revolving fund concept as an ultimate constraint, which I have indicated is not necessarily the case.

Sixth, and very importantly, Mr. Chairman, we need to and are going to collect a body of outside experts in public health and in research to advise us concerning priorities.

In a perfect world, if you are a political scientist you would say, OK, now, Department of Energy, you are responsible for figuring out how you produce, in the least cost fashion, these isotopes for medical use and for research uses. Then some other body who has the expertise in research and pharmaceutical health priorities would be putting in the orders year-by-year. That way we would have access to just that kind of expertise needed to set the priorities straight, and the Members of this body, representing the people of the United States, could make some decisions: What should our overall budgets concerning research and research pharmaceuticals be? What should the share of isotopes be within that budget, et cetera.

We need to get to that model and I am committed to doing so.

[The prepared statement of Mr. White follows:]

STATEMENT OF
WILLIAM WHITE
DEPUTY SECRETARY
U.S. DEPARTMENT OF ENERGY

BEFORE THE

SUBCOMMITTEE ON ENVIRONMENT, ENERGY, AND NATURAL RESOURCES
COMMITTEE ON GOVERNMENT OPERATIONS
U.S. HOUSE OF REPRESENTATIVES

DECEMBER 6, 1993

STATEMENT OF
WILLIAM WHITE
DEPUTY SECRETARY
U.S. DEPARTMENT OF ENERGY
BEFORE THE
SUBCOMMITTEE ON ENVIRONMENT, ENERGY, AND NATURAL RESOURCES
COMMITTEE ON GOVERNMENT OPERATIONS
U.S. HOUSE OF REPRESENTATIVES

DECEMBER 6, 1993

I appreciate this opportunity to testify on the U.S. Department of Energy's Isotope Production and Distribution program, which provides radioactive and stable isotope products and associated services to a wide and varied market. These materials and services are produced and provided through the use of many DOE facilities and scientific capabilities which exist to serve other DOE research and production missions. The ultimate applications of our isotope products include health care, medical and industrial research, manufacturing, agriculture, food preservation, basic research, and education. The Department is committed to ensuring a reliable supply of both stable and radioactive isotopes for these applications.

An adequate supply of medical and research isotopes, produced by either domestic and foreign sources, is essential to maintaining effective diagnosis, treatment, and research capabilities for the Nation's health care system, as well as for supporting basic research and industrial applications that are important to national economic competitiveness.

The production, separation, and application of isotopes has been a mission of the U.S. national research laboratories since the formation of the Atomic Energy Commission. Many beneficial uses of isotopes have originated from this work, including the creation of nuclear medicine, which has been a notable example of technology transfer from the Government isotope programs to the private sector.

In the United States, isotopes are now used in more than 36,000 diagnostic medical procedures daily, 50,000 therapies conducted annually, and close to 100 million lab tests conducted each year. About one in three hospital patients undergoes a procedure involving nuclear medicine, and the total value of these procedures is estimated at $7-10 billion annually. Isotopes provided by the Department have touched the lives of virtually every citizen.

As noted above, our national laboratory complex has been producing and distributing isotopes to support such peaceful applications for over 40 years. Until FY 1990, funding for these activities came via appropriations from various DOE programs. In 1989, Public Law 101-101 established the Isotope Production and Distribution Revolving Fund, providing the program with $16 million. This appropriated amount was provided as initial working capital to make the program self-sustaining.

Despite our best efforts to operate the program on a full cost recovery basis in accordance with P.L. 101-101, we have been unable to do so. From FY 1990 through FY 1992, operating expenditures have outpaced cash receipts by $11 million, and the program has spent $10 million on process development for new products. Consequently, the program has depleted the original appropriation and had to borrow almost $13 million to fund new product initiatives and maintain working capital.

One reason is that the cost of producing isotopes has risen. This is due to a number of factors including aging facilities, less sharing of facilities' costs by other DOE programs who have sustained budget reductions, and production inefficiencies resulting from "piggybacking" on other operations. Isotope production has traditionally been performed at facilities that were designed and operated for other purposes, including weapons research and development -- it has always been ancillary to the missions of the facilities. However, with the dramatic winding down of the Cold War and the corresponding reduction in the scope and extent of defense-related work at these facilities, isotope production has had to bear an increasingly larger portion of these facilities' fixed costs.

A good example of this is the Department's experience with the Omega West Reactor at the Los Alamos National Laboratory. This reactor, proposed to be used to produce molybdenum-99 (Mo-99) (used in 30,000 medical procedures daily in the U.S.) as well as other isotopes, was shut down in December 1992 (due to a high power scram; an unrelated coolant leak was discovered in February 1993) and now requires extensive repairs before restart. Since 1991, the Office of Nuclear Energy has invested more than $7 million, including interest, towards the Mo-99 initiative, on the assumption that its landlord, the Office of Defense Programs (DP), would have a long-term programmatic need to keep the reactor operational. However, based on the nuclear weapons stockpile and related programmatic reductions, DP has determined that it no longer has a mission for the Omega West Reactor, and therefore doesn't need to repair the reactor or support its operations. This places the isotope program in the difficult position of having to fund the repairs and operations in order to establish a domestic supply option for production of molybdenum-99.

This is important because the only other source of Mo-99 (with a half-life of less than three days) on this continent is a 40-year old research reactor owned by the Canadian government. When workers at that reactor threatened to strike last year, they starkly demonstrated the importance of the reliability of supply. But because DP doesn't have a mission for Omega West, the U.S. medical community may have to rely on a single Canadian reactor for the Mo-99 and other important biomedical isotopes used in U.S. medical procedures. Reliance on a single source is not sound public policy. Consequently, we will take actions to ensure a second source of Mo-99 and the other biomedical isotopes.

At the same time that these cost factors are playing out, downward pressure continues to be applied to the prices of isotopes in international markets where the isotope program competes with other suppliers subsidized by their governments. Also, the program must contend with legislative prohibitions on competing with commercial operations on certain high-value products. To remain price competitive under these circumstances, the isotope program must sometimes set prices of some isotopes below the cost of producing those isotopes, resulting in revenue shortfalls. For example, since 1990, we have lost almost $4 million in revenues from stable isotopes as a result of difficulties of competing with Russia in this market segment. Our tritium revenues have fallen from $1.6 million to less than $500,000; helium revenues have been reduced by a factor of three; and a primary customer of another isotope has explicitly communicated to us that its principal reason for purchasing part of its needs from another supplier was the isotope program's relative high prices and the instability in its pricing.

Realizing the extent of the problem, we sought outside advice on how to respond. In mid-1992, we initiated a management study of the program by Arthur Andersen & Co. This study, completed in March 1993, surveyed the status, organizational structure, business practices, markets, and competitors of the program. Arthur Andersen offered recommendations, which fell into the general categories of clarifying the mission and strategy of the program, cutting costs and establishing market pricing, moving toward "best practices" for business, and strengthening the organizational structure.

We have begun to implement some of these recommendations. For example, the study recommended organizational changes, including centralizing marketing functions, financial management, and production operations in the Department's headquarters. We have appointed an individual with strong operations experience to be responsible for isotope production. Implementation of the remaining organizational recommendations is planned for January 15, 1994.

However, we have not yet implemented all of Arthur Andersen's recommendations at this time because, as a result of the study and our own self-examination, we have concluded that we are at a decision point in the program. We believe it would be inappropriate to implement more of the recommendations until fundamental decisions are made regarding the future of the program.

The need for restructuring the program was further emphasized by KPMG Peat Marwick, an independent certified public accounting firm, which, at the request of the Department's Inspector General, conducted an audit of the Fiscal Year 1992 financial statements for the program. Peat Marwick made several recommendations, the most notable of which was that the Department should consider restructuring the program to place it on an efficient and sustainable basis.

We perceive two possible paths for the isotope program. First, to meet the full cost recovery instruction of P.L. 101-101, we would need to narrow our product line to only those isotopes whose selling price covers the cost of production. The risk of this path is the danger of not being able to assure the continued supply of isotopes needed for critical medical procedures. The second path would require the Department to make decisions about the societal value of certain isotopes and the importance of having them available, and then seek appropriations to fill the gap between isotope program revenues and cost.

The second path, which the Department prefers at this time, would be characterized by clear distinctions in approaches toward medical, research and industrial isotopes. In such an arrangement, we would treat certain medical isotopes as simply too important to rely on one producer. This policy is under review by the Administration. As an example of this approach, in the case of molybdenum-99, an independent domestic supply capability would be established. In such a circumstance, we would seek to use FY 1994 funds to provide for facility upgrades and to ensure that we could maintain a production capacity irrespective of the gap between revenues and production cost. With respect to isotopes used for research for which there is no other source, we would produce them with an eye toward recovering as much of the cost as possible. Under this regime, the production of industrial isotopes would be based on our ability to recover costs and the strategic importance of such isotopes.

To help us ensure that we make the best choice as to the future path of the program, we have approached the National Academy of Sciences' Institute of Medicine, Government agencies, and industry users. The Institute of Medicine is studying the issue of the future needs of the National Biomedical Tracer Facility. In a meeting held this November, the Institute of Medicine indicated that they could not give us a short-term response, but that the subject would most likely be addressed in their overall study of the National Biomedical Tracer Facility, which is to be completed in the Fall of 1994. We expect to make some decisions about the program prior to this date. We have also talked with the National Science Foundation, the Department of Health and Human Services, and the Office of Science & Technology Policy. Among the user community, members of the domestic pharmaceutical industry have been very supportive of a Government program to produce medical isotopes.

Irrespective of which path is chosen, we have identified two potential future sources for isotopes (other than the Omega West Reactor). The Advanced Neutron Source reactor is under consideration for construction and operation by the Department to fulfill primary research, education, and training missions. This facility would be available after 2010 to produce isotopes to the extent permitted by its primary mission. The National Biomedical Tracer Facility, proposed by the Society of Nuclear Medicine as an isotope production and research facility, would also contribute to the U.S. isotope supply. However, projected revenues from isotopes from these facilities would probably be insufficient to fully offset the costs of their production.

Currently, the Department is in the process of funding a Project Definition Study to further define the construction, operation and waste management costs and to develop a business plan for operation of the National Biomedical Tracer Facility. With regard to the Advanced Neutron Source, the Conceptual Design is being completed and is likely to incorporate an isotope production capability as good as or better than that currently available at the High Flux Isotope Reactor at the Oak Ridge National Laboratory. Also in FY 1994, the Department is proceeding with an upgrade of the Brookhaven Linac Isotope Producer. This upgrade will enhance the production capability of this facility.

In sum, the Administration is evaluating possible approaches to restructuring the isotope production and distribution program, and the Department will make sure that we include all appropriate stakeholders in the process. For the longer term, we plan to encourage the participation of a broad range of public health experts in the development of the Department's policy on isotopes.

This concludes my prepared remarks. I would be pleased to answer any questions you may have.

Mr. SYNAR. Thank you, Mr. White, I appreciate your comments. Obviously, they are encouraging. Just so you will understand where we are going to go for the next hour or two, we heard this before and we are at a point now, I think Mr. Clinger and I, where we have to use this forum to describe very clearly why business as usual or even business at a little bit different than usual is just not going to get it anymore, and I hope that you will take the next hour as instructive and more importantly as a way to clearly put on the record this equal branches of government's commitment to get this program up and running.

With that, I want to call on Bill Clinger who we are glad to have back from his vacation. He now serves as the ranking member on the full committee, but years ago he helped initiate this whole study. Thank you, Bill.

Mr. CLINGER. Thank you, Mr. Chairman, and thank you, Mr. White, for coming up to testify today about a program that has had serious problems of which this subcommittee has taken a great interest over the years. I would reiterate what the chairman said that we have had assurances in the past that we were going to put this thing on track and it was going to be given the priority that apparently Congress intended for it. Somehow that has not happened, so I think it is important that we have this followup hearing to try and identify with the new administration where we are going, where you hope to go, and I guess as importantly, to give us some indication of when you expect to be able to get there. That has been a problem.

These things tend to drag on and on and we get progress reports with very little progress.

Just a few questions from me at this point. In our 1992 hearing, the Department stated that for 3 years the IP&D program had made considerable progress and oriented itself to a market-based pricing and production system. Yet one of the findings in the Andersen report to which you referred and of which you indicated you propose to implement a number of those recommendations, and the management study of this program states that the IP&D program's current practice is to set prices principally based on the full cost of production for each product.

Based upon this finding, the Department's attempts to set prices to market levels has been unsuccessful. Can you tell us what measures the Department has taken during the past 3 years, plans—it is taking now and proposes to take in the future to implement this type of system and why hasn't the Department been able to do so?

Mr. WHITE. We believe that our pricing currently is and tends to be market-based. Specifically what we have done is made more frequent changes in our price list than once occurred. Let's define what we mean by market pricing.

By market pricing, I will be clear to mean charging as much as the market can bear; or another way to put it is maximizing the revenues. Of course, if you price above a certain level so that you don't have any customers, you don't get any revenues.

Where we can recover costs and more than recover costs, we have tried to do so. I have specifically emphasized to our people that we should retain private marketing expertise if it takes that to make sure that we are as effective in knowing where and how the market is to maximize those prices as we can be. In some cases we do not recover the full cost of production.

Now, if the implication of market pricing is in that circumstance that you discontinue to produce the isotope, we have made a determination to give this program the priority to, in fact, continue to produce the isotope and that, as you know, Congressman, has involved some borrowings to do so, reflecting a priority given the program.

But specifically what we have done is we have had more frequent pricing of the isotopes to better respond to market conditions. What we intend in the future is to designate a particular individual to be responsible for overall marketing and to call upon the private sector, maybe commissioned sales agents, or what we may need in order to have the same type of capabilities as does a Merck or somebody like that.

Mr. CLINGER. You have not appointed that individual to take that role as a marketer at this point?

Mr. WHITE. That is correct.

Mr. CLINGER. I think we are all aware, Public Law 101–101 requires that the IP&D program be self-sustaining. That, of course, has been a matter of some controversy. However, it is my understanding that other countries such as Canada and the former Soviet Union subsidize production of isotopes thereby placing the Department at a competitive disadvantage in terms of a world market.

If that is correct, can you explain the ways in which other countries do subsidize their production of these isotopes and whether we should be emulating their dealing with this program?

Mr. WHITE. Well, I know that in Russia, its reactors have lost some of the defense missions, just like ours, and not only in isotopes, but in aluminum and a number of different other commodities. The subsidies, plain and simple, the State just allocates to the enterprise large credits which are interest free, and I know this occurs within the Russian Defense Department and within MINITOM, its nuclear establishment.

I am told that the Canadian program provides some subsidies for the production of moly-99 and if you want some specific information concerning how those subsidies occur, I might consult with a member of the panel to see if they have some more specific information concerning how those subsidies occur.

Mr. BROLIN. We attempted—in fact, Arthur Andersen attempted as part of the study that we commissioned them to do, we attempted to find out exactly how these subsidies work. Not surprisingly, they were unable to find out exactly how.

There is a relationship between AECL, which produces the isotopes in the reactors and Nordion, which is the commercial enterprise which markets them. But the exact arrangement we were unable to determine.

Mr. CLINGER. It is my understanding that the overhead costs of the IP&D program contribute or add to the cost of the isotope to its users. Can you tell us how you distinguish the overhead costs at DOE from those in foreign countries which basically cause our isotopes to be uncompetitive?

Mr. WHITE. I can tell you first how we do ours and what the nature of the criticism is, and then I will turn to Mr. Brolin to see what we know concerning the cost allocation practices of our competitors.

As you know, the Arthur Andersen report questioned whether we should lower the overhead cost allocation on our isotope production. Not specifically so much, as I recall, to account for the practices of competitors, but to account for the fact that, in many cases historically, there was a secondary mission of isotope production in these reactors and the principal program ought to bear relatively all of the overhead costs.

Of course, you get into very severe, I would say, Departmentwide management programs when you depart from some principles of full cost allocation because then what program becomes the marginal or incremental program as opposed to the principal program becomes, frankly, in a political governmental environment, more a matter of politics. It can become an arbitrary distinction. So we tried for a score card to look at what each program would do if it was allocated its fair, relative pro rata amount of the overhead.

Now, how does that compare with what our competitors do? Do you have some understanding—if I could defer to a member of my panel who may know what Russia and Canada would do.

Mr. BROLIN. I have some understanding from visiting Russia and talking with people in their institutes. In Russia, I think we can assume that they don't have the kind of structured cost accounting standards which we have to follow in our laboratories. They have an opportunity here to obtain hard currency. Hard currency is extremely valuable in their situation, and so I don't believe allocation of overhead costs really plays a role.

In the case of Canada, we understand that there is a contractual agreement between Nordion and AECL. Therefore, AECL, which is in litigation with Nordion, I believe would have an obligation, regardless of how they allocated their overhead, to meet the price that they have agreed to sell the isotope to Nordion for. So, again, our requirements may be different.

Our laboratories have to meet the cost accounting standards and allocate overhead charges consistently.

Mr. CLINGER. Whereas you are saying in Russia they probably don't do it at all and in Canada they have a different cost allocation?

Mr. BROLIN. They have a different relationship between Nordion and AECL, sir.

Mr. CLINGER. I have one additional question at this point, Mr. Chairman. Even if the IP&D program changes pricing to one that would be market based and competitive with other countries, it is my understanding that some manufacturers would still have some serious reservations about doing business with the Department because of the unreliability, the unstable and inconsistent delivery of the isotopes, a feeling in their minds that this is not really a reliable source of supply.

Have you given thought to that? Has the new administration given some thought to that, how you can, in effect, become or at least be perceived to be a more reliable supplier?

Mr. WHITE. Yes. There are two general types of answers, one of which I am prepared to take action on, the other which I think we just need to highlight, and figure out, I would hope together, where we wish to go.

The two points. The one that I am clear where we should go has to do with trying to secure fair pricing or longer term pricing from the M&O contractors that in many cases run these reactors.

For example, the program officials are currently trying to negotiate a 3-year contract for the production of many of the different isotopes. That way we will have more stable needs and pricing profiles so that we are not as volatile in terms of deliverability and price.

However, part of the second overall problem is that we don't have, in most cases, what you would call dedicated facilities that just have this principal isotope production mission, and, obviously, when you take on that particular problem or source of the problem, you run right smack into the middle of large capital expenditures at a time when the overall spending caps for our Department are going lower and lower and lower by billions of dollars, while the environmental cleanup tab comes up by billions of dollars.

So—and that one is the more difficult problem for us, how many tens and tens of millions of dollars would have to be devoted to particular capital projects to have dedicated isotope facilities, which also I might add, Congressman, meet the environmental safety and health standards. You know that our current facilities are aging and that they have had various environmental safety and health problems, which we take very seriously at the Department and which can only be remedied in some cases by substantial amounts of money.

Mr. CLINGER. Without that investment, Mr. White, isn't it true that it is going to be hard to make the case that you are in fact a reliable and going to be a consistently reliable producer in the future?

Mr. WHITE. It will in the case of the announcement I made here that we shall send up to the Hill the reprogramming necessary to get Omega West under way. Given the 30 percent of the international market for isotopes provided by moly-99, I hope that we are going to be making some progress in that direction for that particularly important isotope. And, we need to be in the position to be visiting with our customers and getting customer feedback as to what we could do to get better perception of reliability.

I hope that my clear statement here at this hearing, which is the clearest one you have heard from the administration so far, will be the first step in putting some of those fears to rest.

Mr. CLINGER. But you are planning for a dedicated facility or to use excess capacity as is presently the case? What are you planning for a dedicated facility?

Mr. WHITE. Yes, for moly-99.

Mr. CLINGER. Right, for moly-99. Thank you, Mr. Chairman.

Mr. SYNAR. Thank you, Bill.

Now, gentlemen, we have been in the process of converting the Omega West reactor at Los Alamos to produce these medical isotopes and have spent roughly $8 million, according to our calculations, on this effort so far with what I think you can assess as mixed results.

Mr. Brolin, as you will remember from the subcommittee's August 1992 hearing, we discussed several safety issues that have been raised about the facility by DOE's Los Alamos tiger team. And we questioned you and Mr. Young with respect to whether the safety of the reactor was being adequately addressed by the Department of Energy and who within DOE was going to be held responsible for making sure that the safety problems were going to be addressed.

At that hearing, we were assured that they would be, were we not?

Mr. BROLIN. I believe so, Mr. Chairman.

Mr. SYNAR. All right. On August 20, 1992, 1½ weeks after the subcommittee's hearing, the reactor had two instances where the control rods malfunctioned because of the deterioration of the control equipment, and in September, 1 month after the hearing, a manager at the Albuquerque Operations Office, Mr. Twining, sent a memorandum to the director at the Los Alamos National Laboratory, Dr. Hecker, pointing out Albuquerque's concerns over the deteriorating operations at Omega West.

At this time I would ask unanimous consent that exhibit 3, a memorandum from the Director of the Office of Nuclear Safety; and exhibit 4, a memorandum from Mr. Twining to Dr. Hecker be made part of the record.

[Exhibits 3 and 4 can be found in the appendix.]

Mr. SYNAR. I want to quote the statement on page 2 of Mr. Twining's memorandum concerning the new medical isotope mission. Mr. Twining wrote, "It is essential that the safety programs be exemplary at this facility."

Now, in December 1992, 3 months later, there was an emergency shutdown of the reactor which has been shut down ever since. I also would like to ask unanimous consent that the Department of Energy's type B investigative report dated June 1993 be made part of the record at this time, too.

[NOTE.—The information is filed for the record in the subcommittee office.]

Mr. SYNAR. That report documents the Department of Energy's investigation of the causes of the December emergency shutdown and describes a variety of the shortcomings in the safety operation at the Omega West reactor.

Now, Mr. Brolin, would you agree that the basic conclusions of this June 1993 investigative report is that the message of Mr. Twining's September 1992 memorandum did not get through, and that while it may have been right on target, Mr. Twining's memorandum may have been just a little bit too late to be any good?

Mr. BROLIN. I believe it was not too late. In fact, the additional actions which we intend to take before the reactor is restarted will include correction of all those safety deficiencies as well as the leak which developed or which was discovered, I believe, in February.

We clearly need to do more work on conduct of operations, on upgrading the facility where appropriate, and obviously repairing it. We have had another team, composed of laboratory people plus outside consultants, which visited the Omega West reactor to tell us whether or not they thought it was feasible to restart it and operate it in accordance with the Departmental requirements. We believe it is feasible, but it will probably take us a year to do it. So it will take time, but we fully intend to meet those requirements.

Mr. SYNAR. All right, I ask unanimous consent that exhibit 5 be made part of the record. This is a portion of the 1990 Los Alamos assessment of the remaining life at the Omega West reactor concerning the reactor's cooling system, in particular the underground piping.

[Exhibit 5 can be found in the appendix.]

Mr. SYNAR. The report identified two potential conditions that, if they occurred, would result in permanent shutdown. This item addresses the cooling system piping, in particular, the underground piping.

The report states that, "corrosion and leaks should never be a problem."

After the December 1992 emergency shutdown, you found a leak in the cooling system, didn't you?

Mr. BROLIN. Yes, sir.

Mr. SYNAR. All right. In the underground piping, right?

Mr. BROLIN. Yes, sir.

Mr. SYNAR. Now, gentlemen, this reactor is 37 years old. The building it sits in was built in the 1940's and is even older. We could go on and on with example after example of safety and technical issues here, but I hope you will appreciate what I think is this subcommittee's skepticism concerning assurances by the Department about the safety of its operation and facilities.

Now, there may be good reasons to proceed on Omega West, but I want some assurances, if I could get them, Mr. White, that we are going to know exactly what safety problems do exist and that we are going to want a commitment to resolve these issues promptly and that there will be no more surprises like this.

Mr. WHITE. You have my commitment, Mr. Chairman, and it will be—I will only qualify that to say that the upgrading will take—we will start tomorrow, but it may take some time before the reactor is up and running, but it will not be up and running in an unsafe condition.

Mr. SYNAR. Dr. Knuth, let's go on to what DOE has done since December when that leak was identified. In March you instructed Albuquerque to hold off in any excavation or repair of the reactor without your approval; is that correct?

Dr. KNUTH. Yes, sir, that's correct.

Mr. SYNAR. And you never authorized any repair of the leak until a week or so ago; is that not correct?

Dr. KNUTH. No, that is not entirely correct. We, in fact, wrote a letter in September and directed Los Alamos to place the reactor in a condition for safe shutdown and with eventual decontamination and turnover to EM, Environmental Restoration and Waste Management.

The laboratory called us and requested permission for them to begin repairs at their laboratory at their expense. We agreed that they could——

Mr. SYNAR. When was that?

Dr. KNUTH. When?

Mr. SYNAR. Yes.

Dr. KNUTH. That was about 1½ weeks ago. And about 1 week ago, the laboratory staff did commence digging down to look at the piping to see what——

Mr. SYNAR. When I said you never authorized any repair until a week ago, that was correct.

Dr. KNUTH. No, we have never authorized repair. We still—our direction to them is place the reactor in a shutdown mode with ultimate decommissioning. We in Defense Programs have no programmatic need for the reactor, and it was for that reason that we did not wish to fund repairs of the reactor to bring it back in——

Mr. SYNAR. All right. Dr. Knuth, you have a storage pool at Omega West, do you not?

Dr. KNUTH. I'm sorry?

Mr. SYNAR. You do have fuel in storage?

Dr. KNUTH. Yes, we have fuel in storage in the pool and in the reactor itself.

Mr. SYNAR. About 40 assemblies?

Dr. KNUTH. Forty-nine, I believe.

[The information follows:]

Fuel assemblies are all currently being stored in a safe and approved manner in the fuel storage pool. Prior to the transfer, safety analyses were completed and approved. There are 40 fuel assemblies in the storage pool and no fuel assemblies in the reactor tank.

Mr. SYNAR. Now, the reactor safety analysis report and technical specifications allow four to be stored, don't they? But you have 49, you say.

Dr. KNUTH. We are storing within the allowed specification limit. I don't know what the—most of the elements are in the reactor storage bay itself, in the pool of the reactor. The external storage pool has limited space.

Mr. SYNAR. According to our records, the document for the requirements are in the report Mr. Brolin just alluded to. Are you telling us that is not correct, that the specifications only allow for four?

Dr. KNUTH. In the pool—in the fuel storage pool which is the external reactor?

Mr. SYNAR. Right.

Dr. KNUTH. I believe that is the number. I believe the rest of them are stored within the pool, within the reactor itself. I will check on that, but I am almost sure that the number stored in the external pool are limited. The majority of the fuel elements are lying in the reactor pool itself.

Mr. SYNAR. We will ask you some questions on the record post hearing on this one. Now, in order to remove that fuel, you are going to have to refill the reactor.

Dr. KNUTH. That is correct, sir.

Mr. SYNAR. And unless you fix the cooling system leak, the operation was going to result in additional discharges from the reactor; is that not correct?

Dr. KNUTH. Yes. The water would have—if they had not repaired it, when raising the water level up, would again cause the piping to leak. However, the water that is now in that pool is basically up to drinking water standards.

Mr. SYNAR. Now, every winter special precautions have to be taken at this reactor to keep the cooling pipes and other components from freezing, do they not?

Dr. KNUTH. That is correct, sir.

Mr. SYNAR. And just within the last 2 weeks, Los Alamos finally excavated the cooling system to locate the leaks so the reactor could be winterized; is that correct?

Dr. KNUTH. Not for winterizing. They were looking to excavate to see where the leak was so, if possible, they could commence repairs on the leak itself.

Mr. SYNAR. But you have known for months you were going to have to fix the cooling system no matter whether or not you were going to continue to operate Omega West, right?

Dr. KNUTH. No. If we were not planning to operate it, if the reactor were not going to be operated, we had no plans to repair the leak. We would fill the pool for the time we needed to transfer the fuel elements out of the reactor and then drain the entire system, but we would not go ahead——

Mr. SYNAR. It would continue to leak when you filled it again.

Dr. KNUTH. We would fill it and it would leak while we were transferring elements, but the water there is basically drinking water. It had tritium that was about twice drinking water levels when it was leaking.

Mr. SYNAR. Explain this one more time why not until 2 weeks ago did you excavate that to fix the leak.

Dr. KNUTH. Defense Programs——

Mr. SYNAR. To first find it, then to fix it.

Dr. KNUTH. We have a fairly good idea where the leak is. It was a question, did we want to spend money to repair the leak. In Defense Programs——

Mr. SYNAR. How much is it costing DOE every month just to keep Omega West on standby? Does the number $200,000 per month strike a chord with you?

Dr. KNUTH. That is approximately correct. It is about $1.6 million a year.

Mr. SYNAR. You couldn't find the money to fix the leak, could you, but it cost you $200,000 to let it sit there.

Dr. KNUTH. Well, the cost at the time to repair the leak was estimated to be $1.4 million. We——

Mr. SYNAR. If you knew of this problem a year ago, you could have had it fixed and cut down on the cost of the leak because you are doing $200,000 a month and nothing was happening.

Dr. KNUTH. We basically made the decision that we had no programmatic need for the reactor and were taking steps to reduce our funding to the reactor and to begin operations to transfer this facility to the Office of Environmental Restoration and Waste Management for eventual decommissioning and decontamination.

Mr. SYNAR. Mr. Clinger.

Mr. CLINGER. Thank you, Mr. Chairman.

Mr. White, I understand that funds are being provided to Brookhaven for an accelerator upgrade for isotope production. Was the isotope user or community consulted about the proposal for the Brookhaven isotope producer, either in an advisory capacity or through peer reviews?

Mr. WHITE. Mr. Brolin, do you have——

Mr. CLINGER. Were there any alternative sites considered for this proposal besides the Brookhaven National Laboratory?

Dr. PATRINOS. The Brookhaven Linac Isotope Producer Facility was the most appropriate one that was considered for upgrade because the only alternative, which is the Los Alamos Meson Physics Facility is slated to be shut down in fiscal 1995. So the only remaining one, at least within the family of National Laboratory systems that we had was the Brookhaven BLIP.

Mr. CLINGER. So on the basis of that, since it was the only alternative, you did not feel a need to consult with the user community as to their input?

Dr. PATRINOS. I think we informally consulted with the user community, but we did not form a full blown formal review, no, we did not.

Mr. CLINGER. Is there a payback provision associated with this upgrade of the program?

Dr. PATRINOS. No, Mr. Clinger. To my knowledge, there is not because of the research nature of the accelerator and the research nature of the isotopes produced at the accelerator facility.

Mr. CLINGER. We have had payback provisions in the past. Is this the first time we have not done this?

Dr. PATRINOS. We certainly will try and apply the payback provisions if possible, but nevertheless that will not be the sole criterion by which we will operate, produce, and distribute the isotopes that are produced in the facility.

Mr. CLINGER. I wonder if somebody on the panel could explain what the National Biomedical Tracer Facility is and what the purpose of that facility is. It is my understanding that DOE recently solicited applications for conducting a project definition study for the NBTF and plans to fund five applications at $300,000 each. Is that correct?

Dr. PATRINOS. That is correct, sir.

Mr. CLINGER. What is the estimated total cost of the NBTF?

Dr. PATRINOS. The estimate, as we have it right now, is anywhere between $40 million and $100 million. However, one of the objectives of the project definition study, as well as the study that we have agreed to conduct via the Institute of Medicine of the National Academy of Sciences, the objectives of both studies are to further define the costs and the technical parameters of the National Biomedical Tracer Facility.

Mr. CLINGER. Is this to be funded totally with Federal funds or is there going to be a public-private partnership to develop this facility?

Dr. PATRINOS. We certainly hope that this facility could be built, operated and maintained by the private sector. However, we recognize that it is possible that some upfront Federal funds may be necessary in order to construct the facility and——

Mr. CLINGER. It is unclear at this point what the Federal commitment may be?

Dr. PATRINOS. It is unclear. That is, in fact, part of the activity we have started involving the Institute of Medicine and the whole project definition study activity.

Mr. CLINGER. I guess I would then come back to my original question as to what is the purpose or purposes of the NBTF, because I think that has some bearing on what the private sector would contribute.

Dr. PATRINOS. Yes. The NBTF is supposed to fill the need of accelerator, high energy accelerator-produced isotopes which will represent less than 10 percent of the total market for isotopes, isotopes that are primarily used for research, as well as for some medical applications, both imaging and therapy. They are, as I said, about 10 percent of all the isotopes that are required.

The current facilities are the Brookhaven Linac Isotope Producer Facility and the Los Alamos Meson Physics Facility, and both, as you have heard already today, are aging facilities. LAMPF is scheduled to be shut down in fiscal 1995 and we see the BLIP upgrade perhaps as a stop gap measure, a measure that can help us through the period until NBTF is sited or the issue of the need for the NBTF is decided upon or acted upon.

It is possible that the project definition study, as well as the Institute of Medicine study, will lead us to conclude that NBTF is not really needed and perhaps some additional upgrade at existing facilities, such as BLIP, may actually meet this need. I think we have put in place a process that will help us make the right decision.

Mr. CLINGER. So we have not reached a final conclusion, then, on whether or to what extent you would go forward with this upgrade if it is determined that you can meet the same objective through other routes; is that right?

Dr. PATRINOS. No, we have not yet, sir.

Mr. CLINGER. OK. Since isotopes research, particularly medical research are obviously very important and yet many of them are unprofitable to produce, and we have touched on this already, have you considered alternative ways of funding such production? And I think you alluded to that briefly, Mr. Deputy Secretary. Perhaps you could expand upon that.

Mr. WHITE. Yes. I want to be quite frank in telling you that that is one of the very first questions that I asked myself and asked people within the program area after I was confirmed this summer. We do have large users, purchasers, some of whom the pharmaceutical industry, for example, have, as you know, billion-dollar research budgets and we do have in government research facilities, such as the National Institutes of Health, some very well-funded research efforts themselves. I have encouraged, in the most emphatic way, the people within the Department to look at models of cooperation with private sector universities, pharmaceutical companies, and within the institutes of this government to share some of the funding, and also get some of the leadership that could be provided if you have the public health community and pharmaceutical community directly involved in these projects from the outset.

There are some issues that have to do with the people not wanting the liabilities associated with a reactor, operation of reactors and accelerators, which make—and because of the limited market and the foreign competition which is subsidized, which makes some privatization type model, I am told, impractical.

However, we are aggressively pursuing the various leads—for example, responses we are getting on the facility you just questioned with the university community to see if there are public or private universities that are willing to share in some of these research expenditures. One of the functions of having a panel of outside advisors, as I described in my original statement, is to pick their brains on how the pharmaceutical industry can be more active partners in the investment, as well as purchasers.

So far obviously we haven't done—you know, we have not been able to attract that kind of investment.

Mr. CLINGER. It seems to me one possible avenue, and I wonder if you considered exploring this, would be, since Congress basically wrote into the law a requirement that there be cost recovery for all of these isotopes, would you consider perhaps asking for a waiver from that cost recovery mandate with regard to certain research isotopes which clearly could have great difficulty meeting the cost recovery mandate?

Mr. WHITE. That would be an approach which would be consistent with my statement. I have not consulted with our general counsel specifically the legislation which would be needed to implement what I have represented to you that the revolving fund concept doesn't work. It ought to be revised so we are not just doing ad hoc borrowings, but we need to revise that concept of the revolving fund, and if there is a means it could be done with some kind of waiver or legislatively approved waiver, that is the way to go.

Mr. CLINGER. It seems to me it might be worth considering.

Mr. WHITE. Sure.

Mr. CLINGER. It is almost an impossible task to get full cost recovery for some of these isotopes. Thank you.

Mr. SYNAR. Thank you.

Dr. Knuth, let's come back to you. On September 13, 1993, this very year, you attended a meeting with Mr. White and Mr. Brolin and others to discuss what you should be doing or what should be done about the Omega West reactor; is that not correct?

Dr. KNUTH. I don't believe Mr. Brolin was there. I did attend a meeting with Mr. Berick, of your staff, about that timeframe.

Mr. SYNAR. I ask unanimous consent at this time for exhibits 6, 7, and 8 to be made part of the record.

[Exhibits 6, 7, and 8 can be found in the appendix.]

Mr. SYNAR. Dr. Knuth, exhibit 6 is a September 15 memorandum from you to the Assistant Secretary for Defense Programs recommending that you be given permission to order Omega West to shut down effective September 30, 1993, and this was with respect to the meeting of September 13, 1993, which was held with Mr. White, Mr. Brolin, Mr. Nulton, Mr. Erb, and Mr. Dreyfus.

Dr. KNUTH. That's correct. You are exactly correct. I was referring to another meeting with your staff.

Mr. SYNAR. All right. You were given the authority.

Now, exhibit 7 is a September 27, 1993, memorandum from you to the Albuquerque Operations Office ordering Omega West to be shut down and decommissioned.

Dr. Knuth and Mr. White, was a decision made at the September 13, 1993, meeting or at any time since to discontinue the medical isotope mission of Omega West and decommission it?

Mr. WHITE. No. Specifically the decision that was made, I was just talking——

Mr. SYNAR. So why do you send a memorandum to your Assistant Secretary asking for the authority to decommission the reactor? Dr. Knuth.

Dr. KNUTH. The authority to do this was granted by the Assistant Secretary for Defense Programs who——

Mr. SYNAR. Why did you send the memorandum?

Dr. KNUTH. I sent the memorandum so that we could, in fact, begin the permanent shutdown of Omega West and to begin decommissioning efforts, as I testified earlier.

Mr. SYNAR. Didn't you just hear Mr. White that no decision had been made?

Dr. KNUTH. I am sorry, sir.

Mr. SYNAR. As of September 13, or any time since.

Dr. KNUTH. I am sorry. A decision was made, sir.

Mr. SYNAR. He said it wasn't. Let me ask Mr. White again. Was a decision made at the September 13, meeting or any time since?

Mr. WHITE. To decommission the reactor?

Mr. SYNAR. Yes, and shut it down.

Mr. WHITE. No, it was not. However, I want to—I believe that the characterization of my statements that were made at the meetings, which you see in the memorandum dated September 15, 1993, does reflect the fact that I emphasized to the people that I wanted there to be a vigorous effort to exhaust the sources of funding that might be——

Mr. SYNAR. That is not the question, Mr. White. Did you make a decision?

Mr. WHITE. No.

Mr. SYNAR. Dr. Knuth, who at Defense made that decision?

Dr. KNUTH. The Assistant Secretary for Defense Programs.

Mr. SYNAR. Based on your recommendation?

Dr. KNUTH. That is correct, sir.

Mr. SYNAR. A recommendation that he said had not been made.

Dr. KNUTH. No. This was a separate correspondence after the meeting. A memorandum went to the Assistant Secretary asking for his permission to authorize the shutdown of Omega West.

Mr. SYNAR. Mr. White, did you know that Dr. Knuth had done that?

Mr. WHITE. I did not, but I would have to accept some responsibility in this regard, Congressman. I am not trying to shirk the responsibility of saying that I indicated to him that—and to the various officials that I expected a report——

Dr. KNUTH. May I complete my statement, sir?

Mr. WHITE. That I expected a report back to me concerning the sources of funding that might be available, as I just——

Mr. SYNAR. Mr. White, you need to know what I am about to tell Dr. Knuth. You know, based on that memorandum, people retired at Omega West because of that?

Dr. KNUTH. People were transferred, but no operators were transferred. Yes, sir. Let me complete my statement. We indicated to the laboratory that we wanted them to commence preparations to shut down the reactor.

We provided $1 million in extra funds to do just that. The instructions were to make no movements——

Mr. SYNAR. The decision was never made, Dr. Knuth. Listen to the guy who is your boss. The decision was never made.

Dr. KNUTH. The decision was made by my boss, sir, to do that.

Mr. SYNAR. Based upon what? Who did you work for?

Dr. KNUTH. I work for Mr. Victor Reis, who is the Assistant Secretary——

Mr. SYNAR. Who does he work for?

Dr. KNUTH. He works for the—Mr. White.

Mr. SYNAR. In the meantime, on September 20, Los Alamos writes you, Mr. White, asking what to do about Omega West. On October 14, Dr. Brolin's deputy sends out a letter, exhibit 8. Is it out—on your behalf, telling Los Alamos not to do anything that would make it more difficult to restart the reactor.

This, of course, directly contradicts this memorandum, previous instruction, Dr. Knuth.

Dr. KNUTH. You never let me finish my statement.

Mr. SYNAR. Go ahead.

Dr. KNUTH. The instructions to the laboratory were to commence efforts to decommission the reactor and place it in a safe shutdown condition, but to take no steps to make it an irrevocable decision that the reactor could not be restarted. They were not to lay off the operators who actually defuel the reactor, and they would be needed if they made a decision to start the reactor.

Mr. SYNAR. Why do that at all if the decision hasn't been made, Dr. Knuth.

Dr. KNUTH. The decision was made in Defense Programs. We had no mission for that reactor and——

Mr. SYNAR. Who made that decision?

Dr. KNUTH. The Assistant Secretary for——

Mr. SYNAR. And who does he work for?

Dr. KNUTH. He works for——

Mr. SYNAR. And what did Mr. White say?

Dr. KNUTH. I just heard what he said. That is the first time I was aware of it.

Mr. SYNAR. It is a good thing the people at Los Alamos—Mr. White, who is running the Department?

Mr. WHITE. I am, along with the other confirmed appointees.

Mr. SYNAR. All right, I want to ask unanimous consent to make exhibit 9 part of the record.

[Exhibit 9 can be found in the appendix.]

Mr. SYNAR. This is a memorandum from you, Mr. Brolin, to Mr. White dated August 5, 1993. This memorandum recommends that Omega West Medical Isotope Project go ahead and outline the reasons why it is important to do so, the U.S. reliance upon a single AECL reactor, for example. It is a good memorandum, Mr. Brolin.

Mr. White, this memorandum was the subject of the September 13, 1993, meeting referred to earlier, was it not?

Mr. WHITE. Yes.

Mr. SYNAR. You have not acted on this memorandum, have you, until today?

Mr. WHITE. Well, within the last week, yes. You are correct on that.

Mr. SYNAR. This memorandum has been on your desk for 4 months, hasn't it?

Mr. WHITE. Yes.

Mr. SYNAR. I recognize that unraveling the isotope program isn't easy, but we are still trying to do so ourselves. This hasn't been a priority at DOE, has it?

Mr. WHITE. It has been. I was at a meeting——

Mr. SYNAR. Hold it. Did that thing sit on your desk for 4 months?

Mr. WHITE. It did not sit on my desk. I did have a number of meetings and conversations to try to answer some very basic questions.

Mr. SYNAR. Let's ask about that. Have you completed a NEPA review of the Omega West medical isotope mission? You haven't even done that, have you?

Mr. WHITE. I don't know the answer to that.

Mr. BROLIN. We have completed the environmental assessment and it is in the Office of the Assistant Secretary for Environmental Safety and Health for review.

Mr. SYNAR. It is not completed, is it?

Mr. BROLIN. It is not completed in the sense of being issued.

Mr. SYNAR. All right, I would like to ask unanimous consent to that exhibit 10 and exhibit 11 may be part of the record.

[Exhibits 10 and 11 can be found in the appendix.]

Mr. SYNAR. Now, these are a statement of work for the Landis committee and a cover letter from Mr. John Landis to Secretary O'Leary transmitting his panel's report on the Fast Flux Test Facility. That reactor cost almost three-quarters of $1 billion to build. The Department of Energy is now spending over $5 million a month to keep it in hot standby.

What I would like to do here is read Mr. Landis' cover letter. "We have therefore recommended that the facility (FFTF) be shut down if you are satisfied that a crucial issue outside the scope of our assignment can be resolved. This issue is whether or not the Department's remaining test reactors will have the capability to carry out the various missions they will be asked to perform, including the vital mission of supplying urgently needed medical radioisotopes if the FFTF is permanently shut down."

Mr. White, first of all, you were going to do a study of whether you should shut down the Department's newest research reactor. Why wasn't Mr. Landis tasked to examine whether or not the Department's remaining reactors will be able to carry out their missions, including isotope production? Isn't that a fundamental question when the average age of your remaining reactors is about 30 years old rather than whether the FFTF can pay for itself?

Mr. WHITE. Specifically, it is a fundamental question of what the capability of the Department shall be in the future to produce isotopes. Why Mr. Landis was not asked that as opposed to the question that he was asked is an answer that I cannot give you.

I know that this—he was assigned a specific mission and question as defined in his assignment, which was more narrow than our departmentwide isotope capabilities.

Mr. SYNAR. But this whole study was the basis of your announcement today?

Mr. WHITE. Yes.

Mr. SYNAR. So how can you make an announcement on an analysis that is at best incomplete?

Mr. WHITE. Well, I will take a shot at that and then ask my colleagues if they want to comment. I believe that if we start up the Omega West reactor and continue with some of the capital improvements and get out of this revolving fund mode, that we will have facilities which can produce the variety of medical isotopes for which there has been historical demand. And, that if we were to continue the operations of the Fast Flux Test Facility, it would be extremely costly.

Mr. SYNAR. Let's look at this. Here is another case where we don't even know what the Department's long-term policy and commitment to isotope production is, do we?

Mr. WHITE. I would not agree with that.

Mr. SYNAR. All right. The Landis committee made a special point of making this statement because they were concerned that the Department of Energy was going to shut down this reactor without even really knowing whether it was needed for isotope production. Now how does the testimony that you are giving today, Mr. White, which suggests that you may not have fully developed a policy on isotopes until after the Institute of Medicine report is out a year from now, apply to your decision, announced this morning, that you have investigated all of DOE's missions and FFTF isn't needed? How do you do that?

Mr. WHITE. I believe that the decision on the FFTF was made based upon both the Landis report and the knowledge we had concerning the other facilities which were available at some cost, I might add, to produce isotopes. Although I was not personally part of that decision, I believe we did have both the information we have concerning our isotope program and its facilities, as well as the Landis report in hand.

Mr. SYNAR. I would like to ask unanimous consent that exhibit 20 be made part of the record. It is the letter from the Department to the Washington State Congressional Delegation dated December 6, 1993. It refers to this independent review team commissioned by the Department to evaluate the multimission role, which is the Landis group. All right. No, go ahead.

[Exhibit 20 can be found in the appendix.]

Mr. CLINGER. I just have a couple of questions. During the 1992 hearing some of you were present, weren't you?

Mr. BROLIN. I was, yes, sir.

Mr. CLINGER. You were the only one. The Department stated that you had been working with the private sector and that you would intensify those efforts to find a cooperative way of meeting their needs for isotopes. I guess the question then becomes since that hearing in 1992 what efforts has the department made, any additional measures that you have taken to follow through with this commitment to really explore with the private sector how you could come up with a viable program?

Mr. BROLIN. We have done a number of things, Mr. Congressman. I made several visits to our major customers to discuss one-on-one with them their concerns with the performance of the program and what we might do about it. The Arthur Andersen report itself was the most comprehensive visit between—as a surrogate for the program and the private sector. Subsequently we have had other discussions with the private sector. So there were a number of interactions.

Immediately after the hearing, I sat down with the President of the Institute of Nuclear Medicine, I believe, as well as the chairman of mediphysics, and discussed specifically with them the program and they also discussed the National Biomedical Tracer Facility. So there have been a number of sessions.

Mr. CLINGER. So it really was Arthur Andersen who was sort of the intermediary on those discussions with the private sector?

Mr. BROLIN. Yes, sir.

Mr. CLINGER. And I presume a number of the recommendations which Arthur Andersen made arose out of some of those contacts with the private sector?

Mr. BROLIN. Yes, sir.

Mr. CLINGER. Of those recommendations which were contained in the management study of the IP&D program, are there any that you in the department disagree with or would find unworkable? You mentioned that you were proposing to implement some of those recommendations, were studying others, and that there were some that you did not feel were applicable. Can you give us an idea of which recommendations you would find unworkable?

Mr. BROLIN. I believe the context in which Mr. White mentioned—this is the Arthur Andersen report—was based on the current context; namely, Public Law 101–101, which requires, as you know, full cost recovery. Therefore, some of their recommendations would lead, if implemented, to discontinuing production of certain isotopes. And within the context that Mr. White just mentioned, the production of those isotopes would not be discontinued, so in that sense we wouldn't be strictly following through on the Arthur Andersen report.

But within the context in which they made the report, and I would have to look obviously at every specific recommendation again to be absolutely certain, in general, we did not disagree with the recommendations. We thought it was a good report.

Mr. CLINGER. As a result of that report, did I understand, Mr. White, that you are going to be proposing legislation to implement some of those recommendations? Or do some of those recommendations require——

Mr. WHITE. Yes.

Mr. CLINGER [continuing]. Legislative activity?

Mr. WHITE. I could give you today orally, or I would suggest that we do so in writing, a response, one-by-one, to the various items in the Arthur Andersen report.

Mr. CLINGER. That would be helpful.

[The information can be found in the appendix. See DOE's response to the chairman's question 3a.]

Mr. WHITE. Quite a number of those items within the Arthur Andersen report could be categorized as being along the lines of, well, you are not really running this as a revolving fund program because there are some isotopes that are not standing alone, and which bodes a problem for the long run cost recovery of the program. So there are some of the recommendations that Arthur Andersen made that are contrary to the policy of simply discontinuing the production of some isotopes.

They had some recommendations which had merit. For example, some of their recommendations concerning the marketing of isotopes that are being—and some that are being taken care of—and we have a deadline for most of those of January 15, 1994.

Mr. CLINGER. So a number of the recommendations in the report can be implemented administratively——

Mr. WHITE. Yes, sir.

Mr. CLINGER [continuing]. By the executive branch, but some would require legislative action?

Mr. WHITE. In particular, if we wanted to get out of the revolving fund model.

Mr. CLINGER. And you have indicated that you are——

Mr. WHITE. Yes.

Mr. CLINGER [continuing]. Moving in that direction?

Mr. WHITE. We will continue to talk to our general counsel about what we would need to do.

Mr. CLINGER. If the Department proceeds to decommission the Fast Flux Test Facility, which the chairman has been discussing and which has been identified as able to produce isotopes, is it your position or did you consider how the standing down of that facility would be made up with perhaps the Omega West reactor, Brookhaven National Laboratory accelerator? Would they provide enough capacity to offset what the standing down of the Omega West facility would mean?

Mr. WHITE. It is my understanding that that is, in fact, the case, and Mr. Brolin may have a particular comment on that, since I do not buck responsibility ever. I did not participate in that decision, and I might ask—but I mean I am not saying I am not responsible for it. I am going to ask Mr. Brolin to address specifically the input into the isotope consequences of that decision.

Mr. BROLIN. I am—you mentioned, excuse me, Mr. Congressman, you mentioned FFTF and then the Omega West reactor?

Mr. CLINGER. Well, since FFTF is able to produce isotopes and if you are going to decommission it, obviously that means that you are going to have one less facility able to produce isotopes. Are you confident that the remaining facilities are able to make up the slack?

Mr. BROLIN. Yes, sir. In fact, FFTF is not and has not for the past couple years produced any isotopes. Of course, it hasn't been operating. We have ample capacity with the remaining test reactors to produce more than the number of isotopes and more than the quantity of isotopes for which we have demand.

We considered not just the Landis report, but our own internal investigations. We looked quite thoroughly into the isotope capability of FFTF. I spent several hours one evening going over with Westinghouse and two consultants which they had hired, their business analysis of FFTF and its production of isotopes and was satisfied, one, that the business analysis was fundamentally flawed, and, two, through that and other knowledge that I have and have gained since, that we have adequate capacity without FFTF for isotope production.

Mr. CLINGER. OK. Thank you, gentlemen. Thank you, Mr. Chairman.

Mr. SYNAR. Thank you, Bill. Thanks for coming in today. I do appreciate it.

I would like to ask unanimous consent to enter in the record exhibits 12 and 13.

Exhibit 12 is the long-range plan for the Department of Energy's research reactors, which was supposed to be completed in September of this year in response to recommendations of the GAO report prepared at the request of this subcommittee last year.

Exhibit 13 is the DOE's Controller's letter to this subcommittee, committing you to provide this report.

[Exhibits 12 and 13 can be found in the appendix.]

Mr. SYNAR. Now, first of all, we are talking about decisions literally affecting billions of dollars worth of equipment, research and programs. Now, this is supposed to be a long-range plan for these reactors. Mr. White, you sent us the executive summary. Where is the rest of the report?

Mr. WHITE. Where is the rest of the report?

Mr. SYNAR. Yes.

Mr. WHITE. I am informed that there are—there is other backup to the——

Mr. SYNAR. This is the report, is it not, Mr. Brolin.

Mr. BROLIN. Yes, sir.

Mr. SYNAR. That is the point. This is nothing but a back-of-the-envelope description of what various people at DOE think they will do with these reactors. If you want to know what research missions the Department of Energy is going to have into the next century, or what reactors will be used to carry them out, you have a table of blanks and X's instead of references to identifiable research plans.

Now, gentlemen, these questions involve billions of dollars of facilities and programs. I want to know when we are going to see this plan completed.

Mr. WHITE. Could I——

Mr. SYNAR. Sure.

Mr. WHITE [continuing]. Answer that? Since about August 10, the senior managers in this Department have been engaged in a very extensive long-term planning exercise and strategic planning exercise, which we started practically anew, within the research programs, Mr. Chairman, within defense programs, basic science, applied sciences, energy, and environment. The Secretary of Energy has announced this strategic programming activity and it is nearing its completion.

Mr. SYNAR. Mr. White, you are familiar with the fact that Ms. Krebs and Mr. Dreyfus signed this November 22, 1993, and November 12, 1993?

Mr. WHITE. Yes.

Mr. SYNAR. So they didn't take into account any of this august vision?

Mr. WHITE. They have.

Mr. SYNAR. Why isn't it in the report?

Mr. WHITE. Because that process has just been winding up and I am specifically responding to the point of why——

Mr. SYNAR. So what I have in front of me is not the long-range plan?

Mr. WHITE. It is not the long-range plan for the Department of Energy, as a whole, and for the basic functional areas.

Mr. SYNAR. What is it then? Because it says here, long-range plan for utilization, retirement, and replacement of the Department of Energy's nondefense test and research reactors. If it is not what you say it is, what is it?

Mr. WHITE. It is a plan for just what it says, for the test and research reactors, but as a matter of public policy and administration, what we are trying to do, Mr. Chairman, is we are trying to make sure that the basic research, energy research and defense programs themselves, have strategic plans.

Mr. SYNAR. Well, I would suggest what you have given us is a desperate attempt to cover yourself with this subcommittee and its request.

Mr. White, the report that we are talking about here was not reviewed by Assistant Secretary Tara O'Toole or the Office of Environment, Safety and Health, was it?

Mr. WHITE. I do not know who was asked to——

Mr. SYNAR. Mr. Brolin, do you know that?

Mr. BROLIN. I would have to check the record.

Mr. SYNAR. It was not, we have been informed. And the question is why not? Because, as you can see, her signature is not on the cover. So could you tell me why the plan for operating half a dozen DOE nuclear reactors, most decades old, wasn't even subject to review by the Office of Environment, Safety and Health.

Mr. BROLIN. I believe I can answer that, Mr. Chairman.

Mr. SYNAR. OK.

Mr. BROLIN. One, the fact that her signature isn't on here doesn't mean she didn't concur with it.

Mr. SYNAR. She did not, we asked her.

Mr. BROLIN. But, as I say, so I can't verify that.

The fact is what we are looking at here is a question of two things: One is programmatic need, which, of course, isn't the responsibility of ES&H; and the second is lifetime of the reactors, which is also primarily the programmatic responsibility.

The safety people look at these reactors essentially every day. We maintain that they are safe to operate and the safety people look over our shoulder and make sure that they are satisfied with that. When you are looking at a programmatic document such as this, it is not at all unusual that ES&H would not concur. They would, however, if we were to get to the point of extending the life of these reactors, beyond the design life, they would certainly look at any such decision. But the thrust of this is that these reactors are, although they are "old," they have been, in many cases, routinely upgraded and they are safe to operate for many years to come based on our technical analysis.

Mr. SYNAR. Mr. White, let me ask you, why weren't they reviewed by ES&H and why shouldn't they be?

Mr. WHITE. I think there is some good likelihood that they should have been. And I am glad that you have brought this to my attention and I will talk to Ms. O'Toole and try to determine what the best entry point is for their involvement in long-range planning decisions.

I can see the point that you make, that the earlier that particular program area is involved in some of these long-term planning decisions, the more sound the decision is likely to be from an ES&H standpoint.

Mr. SYNAR. All right. We have already talked about Omega West and the FFTF, and according to the long-range plan that we have just discussed, it appears the department, Mr. White, is going to shut down virtually all of its research reactors within the next 2 years, except for the Advanced Test Reactor [ATR] in Idaho, which you hope to run until about 2014. And to replace all these reactors, you are going to build a new reactor, the Advanced Neutron Source [ANS]. Now the administration requested funds to begin construction of the ANS in fiscal year 1994, did it not?

Mr. WHITE. Yes.

Mr. SYNAR. About $26 million in construction funding?

Mr. WHITE. I believe that is correct.

Mr. SYNAR. And the total project cost is now estimated by DOE to be about $2.75 billion; is that correct?

Mr. WHITE. I do not know what the most recent estimation of cost is.

Mr. SYNAR. Mr. Brolin is shaking his head yes.

Mr. BROLIN. Yes, sir.

Mr. SYNAR. So given DOE's plans, if we are going to have the capability of producing reactor-derived isotopes into the next century, we are going to have to rely on the ANS, aren't we?

Mr. WHITE. Rely on ANS and some other facilities.

Mr. SYNAR. So it might be advisable, wouldn't it, Mr. White, before we spend several billion dollars, to know what the isotope production capability of your reactor is going to be, might it not?

Mr. WHITE. Yes.

Mr. SYNAR. I would like to ask unanimous consent to enter in the record exhibit 14. This is a summary of the design capabilities of the Advanced Neutron Source.

[Exhibit 14 can be found in the appendix.]

Mr. SYNAR. It states that the ANS design goal is to produce isotopes essentially at the same level of production as the single existing research reactor, the High Flux isotope reactor at Oak Ridge, one of the reactors ANS is intended to replace.

Now in reality, we are not replacing only the Oak Ridge reactor, are we? We are essentially replacing every reactor.

Dr. Brolin, as you know, we asked the Department of Energy to provide to the subcommittee documentation of how the department arrived at this specific design goal. The department did not base the isotope design goal on an analysis of all the Department's future isotope needs, did it?

Mr. BROLIN. I don't know what this requirement was based on. It was my understanding, and I need to verify this, that the ANS has isotope production capabilities more than enough to replace both HFIR and HFBR at Brookhaven. This doesn't say that, I agree. But that is my understanding and that is what I have to confirm. In addition, I might add, the ATR has additional isotope production capability which is utilized as well.

[The information follows:]

A design goal of the Advanced Neutron Source is to have radioisotope production capability as good as or better than the High Flux Isotope Reactor, but not on an isotope for isotope basis. If we were to perform the requested calculations comparing the Advance Neutron Source to the High Flux Isotope Reactor, the results would show higher specific activities and quantities for some isotopes, about the same for other isotopes, and somewhat less for the remaining isotopes. At this stage of the design, these calculations would not provide a basis to change the ANS design to increase radioisotope production capability at the expense of neutron scattering and materials irradiation design goals. It is appropriate to perform these calculations during the Title II design process.

A full analysis by Oak Ridge will be accomplished during the Title II design phase of the ANS project, currently scheduled during 1996 and 1997.

Mr. SYNAR. I would like to ask unanimous consent that exhibit 15 be made part of the record.

Will you verify this for the record, Mr. Brolin. This is the table that shows nontransuranic isotopes that ANS will produce.

Mr. BROLIN. Yes, sir, it appears to be.

[Exhibit 15 can be found in the appendix.]

Mr. SYNAR. Mr. White, when the subcommittee asked the Department of Energy to provide us with an analysis of the quantities of the nontransuranic isotopes that could be produced by the ANS, the Department informed us that it was premature to provide that information.

You have a plan that calls for shutting down almost all of DOE's research reactors. You are proposing to build a $2.7 billion reactor to carry your entire reactor-based research and isotope production activities into the next century. Your design review shows that you are going to have a capability for producing nontransuranic isotopes that are less than can now be produced in the single reactor at Oak Ridge. You have spent $87 million on the design of the reactor. You budgeted another $26 million for construction in 1994. And you have requested that Congress fund its construction.

Mr. White, explain to the subcommittee why it is premature to tell us the quantities of the nontransuranic isotopes that the ANS design is capable of producing.

Mr. WHITE. I don't know from my own knowledge that it is premature. I do know that the money that was appropriated for fiscal year 1994 is not for construction, but it is for continued design; and for a project that is this large I don't know where we exactly are in the design process that would allow one to identify all the isotopes that might be produced. I would ask my colleague if he could comment on why we do not have that information available or if in fact, it is not available.

Dr. PATRINOS. Insofar as the Advanced Neutron Source, the conceptual design report has been completed, as well as the cost evaluation.

We had expected to request construction funding in 1994. We did not. We perhaps will be requesting it for 1995. I do not know the exact status of the analysis with respect to the isotope production.

However, if I may add just one comment. That is the future needs of isotopes in medicine is an issue that will be taken up by the Institute of Medicine, which is commissioned by us for the accelerator-produced isotopes needs. However, they may address the broader need of medical isotopes. And it is possible, I am not saying it is likely or very probable, but it is possible that, in fact, future needs of medical isotopes will diminish as new advances in nuclear medicine and molecular biology and biotechnology overtake some of the present needs.

Mr. SYNAR. Our problem here, gentlemen, is that Oak Ridge has the capability to perform the analysis I just asked you for. We asked the primary investigator when he was contacted by this subcommittee, and he said the work could be done. I just want to know why the Department has refused to provide us the information.

Mr. WHITE. Mr. Chairman, if we are refusing to provide you with information that is readily accessible to us, that is wrong and we ought do it.

Mr. SYNAR. All right. According to the independent cost estimate [ICE] prepared in September 1993, there are significant technical risk factors with the conceptual design of the ANS reactor and its costs are likely to be higher because of some unresolved technical issues requiring additional R&D. In fact, the ICE estimated that the project schedule would likely slip at least a year because of these problems. Is that correct?

Mr. WHITE. I cannot tell you the answer to that.

Mr. SYNAR. Mr. Brolin, is that correct?

Mr. BROLIN. I don't know, Mr. Chairman.

Mr. SYNAR. Well, have you ever read the independent cost estimate?

Mr. BROLIN. I received a briefing on it, but I don't believe I have read it.

Mr. SYNAR. Has anybody at this table read it?

Dr. PATRINOS. I have not.

Mr. SYNAR. Who is in charge of the Department, Mr. White?

Mr. WHITE. The Secretary and I are. I will tell you, Mr. Chairman, that we spend some considerable time discussing the ANS and——

Mr. SYNAR. It is a $2.7 billion decision and somebody ought to be reading the material on it.

Mr. WHITE. And there are—and there has been a tremendous amount of attention placed on the topic of whether we——

Mr. SYNAR. But the five people sitting at this table haven't given it any attention because nobody said they have even read the darn thing.

Mr. BROLIN. I didn't say that. I said, Mr. Chairman——

Mr. SYNAR. You said you were verbally briefed. You said you hadn't read it. Do you want to change that?

Mr. BROLIN. Not on that particular point, but that is not the only information available to support the project cost estimate. I spent a whole day at Oak Ridge where this subject was discussed, and, frankly, I think the conceptual design report is extremely detailed for a project of this nature.

Mr. SYNAR. All right. Because you are considering a change from high enrichment uranium fuel to medium or low due to the nonproliferation consideration, it is possible that the ANS specifications, the cost estimates, the completion date may change significantly, that the project costs could increase and that the reactor may deliver a lower performance. That is correct, is it not?

Mr. WHITE. On the Advanced Neutron Source, you are referring to?

Mr. SYNAR. Right.

Mr. WHITE. I would—I can't answer all the technical details, but certainly I would say that we cannot foresee and pretend to foresee with any certainty right now, the state that the ANS is right now, what it will look like and what its final performance characteristics will be in the year 2000.

Mr. SYNAR. We don't know when we are going to have it and we don't know what its capabilities are, do we?

Mr. WHITE. We know a fair amount about the design, but we are far from knowing what this thing will ultimately do.

Mr. SYNAR. But the point is, we hope the other reactors will keep operating according to your long-range plan. And none of these plans are based on any kind of analysis that is systematic of what isotope production requirements of the Department will be. Isn't that correct?

Mr. WHITE. I believe that I have to tell you that we will make sure and——

Mr. SYNAR. That is a yes or no, Mr. White. I mean, this analysis is just not there, is it?

Mr. WHITE. We do know what the isotope requirements are and we will make sure that we have the reactors to produce them.

Mr. SYNAR. What were you basing that on? Do you have that, because we sure don't have that in front of us.

Mr. WHITE. We have the—we know what the—I have information concerning what the sales are and what isotopes have been requested for which there is unsatisfied demand.

Mr. SYNAR. If you would submit that for the record, we would appreciate it.

Mr. WHITE. OK.

[The information can be found in the appendix.]

Mr. SYNAR. Let's turn to the accelerator-produced isotopes. Consistent with previous DOE budgets submitted during the Bush administration, this administration's fiscal year 1994 budget did not contain any funding to run the linear accelerator at Los Alamos (LAMPF). To your credit, your fiscal year 1994 budget includes the beginning of a $6.5 million upgrade of the BLIP facility at Brookhaven National Laboratory to try to close the gap that will be created in accelerator produced isotopes when Los Alamos shuts down. But according to Brookhaven, its operating funds for fiscal year 1994 are being cut roughly 10 percent from last year and no source of funding to actually run the upgraded BLIP facility has been identified.

Mr. White, it sounds to the subcommittee like one step forward and two steps back. On the one hand, you are committing $6.5 million to upgrade the Brookhaven physical capability, but you are not funding them to operate it. Why is that?

Mr. WHITE. Perhaps I could call my—if that is true, that would make no sense. And I would call on my colleague to respond to that.

Dr. PATRINOS. I would be delighted to. The upgrade of the BLIP facility will be completed in fiscal 1996, during which time we would be considering funding the activity to operate it.

The 10 percent cut you are referring to is this fiscal year, and it is the result of cuts across the entire Office of Energy Research's budget, reflected in many of our contractors, including our national laboratories.

Mr. SYNAR. All right. Let me see, so you are not going to hire anybody, you are not going to do any planning, you are not going to outline research, you are just going to let it sit there until the time you open the door?

Dr. PATRINOS. We fund—I don't have the numbers at my fingertips, but we have considerable funding at Brookhaven National Laboratory's, Biology and Medical Divisions. And we expect, if indeed the BLIP upgrade will happen and will meet the need of accelerator-produced isotopes, we will be putting a commensurate amount of funding in the operating category in order to operate that facility. It would make no sense otherwise.

Mr. SYNAR. Are you going to request funds for LAMPF running into fiscal year 1995?

Dr. PATRINOS. No, we expect to shut down LAMPF in fiscal 1995. That is our plan as of right now.

Mr. SYNAR. I want to ask unanimous consent, exhibit 16 be part of the record.

[Exhibit 16 can be found in the appendix.]

Mr. SYNAR. Mr. White, this is an October 14, 1993, Federal Register solicitation for $1.5 million in grants for the project definition phase of the National Biomedical Tracer Facility. It was put out over Dr. Decker's signature. I am sorry that Dr. Decker is not here to explain it for himself, but as you point out in your testimony, this proposed facility is expected to provide accelerator-based isotopes in the future.

Now my question is why is this not a normal procurement and why are you offering to give up to five grants at approximately $300,000 apiece to conduct this project definition study?

Mr. WHITE. I will give a brief answer and then defer to my colleague for more detail.

We are trying to explore ways, as I had indicated in my response to the question to Congressman Clinger, to come up with some innovative ideas for commercial operation of some of these facilities given the mandate that we have had, the statutory mandate for cost recovery and the like.

The Arthur Andersen report, specifically, for example, mentions the fact that there were universities that might be interested in funding the operations of some facilities. And that is one of the important things that we want to check, the interest, with this particular solicitation.

Now as to why we didn't go a step farther, I will defer to my colleague.

Mr. SYNAR. Why weren't the normal procurement requirements used, Dr. Patrinos.

Dr. PATRINOS. Could I ask for a clarification about the normal procurement?

Mr. SYNAR. Well, the normal procurement doesn't provide for grants. It would provide a competitive RFP. You didn't do that.

Dr. PATRINOS. The National Biomedical Tracer Facility presents the department with rather unique circumstances. First of all, DOE's application of OMB Circular A–76 within the Department precludes us from competing our national laboratories with the private sector. Moreover, we were aware of the private sector's interest. At least one particular group is interested in building and operating the National Biomedical Tracer Facility.

So the avenue we took with the project definition study was in order to further define the details of the National Biomedical Tracer Facility, to explore many of the environmental waste issues associated with it, and also explore the issue that Mr. White referred to, and that is whether the private sector could operate it in a sustainable manner. This process was——

Mr. SYNAR. That is a good answer. It is not the answer to my question. Why wasn't the normal procurement system used? I mean, somebody had to make a decision.

Dr. PATRINOS. Well, because we cannot compete the national laboratories with the private sector, we first have to make a determination whether——

Mr. SYNAR. With what?

Dr. PATRINOS. Pardon?

Mr. SYNAR. Go ahead.

Dr. PATRINOS. We cannot issue a RFP for which both our national laboratories and the private sector can compete. We can only have our national laboratories compete for a facility such as the NBTF, only if we can determine that the private sector is interested in or that they cannot operate it in an economically sustainable manner. That is why we commissioned the National Academy of Sciences——

Mr. SYNAR. Am I wrong in this? What the Department is supposed to be doing is not soliciting bids for the construction of the NBTF, but rather completing a project definition study, right?

Dr. PATRINOS. That is correct.

Mr. SYNAR. The directive by Congress to DOE was to conduct a conceptual design study so we can understand what the annual actual needs are of the medical community and what the facility is supposed to look like and how much it will cost and so forth, correct?

Dr. PATRINOS. I think I have with me a copy of the direction in our conference committee report, and I can quote, "the Department is urged to address the situation by providing adequate funds to begin the one year NBTF project definition phase, as outlined in the 1991 DOE report."

Mr. SYNAR. Right.

Dr. PATRINOS. Which is what we did. That is what the——

Mr. SYNAR. That is the design phase; that is not the competing. I mean, you just made my case. So if Mr. Decker or you were so worried about competing with the non-Federal parties under A–76, the test would be whether private parties want to compete for the conceptual design study, right?

Dr. PATRINOS. That is correct.

Mr. SYNAR. Not the facility.

Dr. PATRINOS. That is correct.

Mr. SYNAR. But DOE didn't do that. DOE jumped over the question of what the facility should be, and went to the next issue of whether some other entity—other than the Federal Government—should actually operate it, did you not? Didn't you skip over it?

Dr. PATRINOS. No, no, we did not.

Mr. SYNAR. All right. What the OMB Circular A–76 says, and what DOE's regulations say, is that the government should rely on the commercial sector to provide commercial products and services. It is not all clear how you or Dr. Decker were able to conclude that building and running this facility was going to be a commercial product or service, but we are interested in finding out.

Dr. PATRINOS. That is correct.

Mr. SYNAR. Now, Mr. White, this facility is estimated to cost $100 million, as I noted. And Dr. Decker seems to think that this is a commercial project or service. Now DOE Order 4510.1B, the Economic Assessment of Commercial Activities, requires the Department to prepare a formal A–76 cost comparison study. Was that cost comparison study done?

Mr. WHITE. I do not know the answer to that question.

Mr. SYNAR. Dr. Patrinos, was that done?

Dr. PATRINOS. I am aware that an internal ad hoc business design group met.

Mr. SYNAR. Was it done, Dr. Patrinos.

Dr. PATRINOS. I am not aware of.

Mr. SYNAR. No is the answer, correct?

Dr. PATRINOS. I am not sure, Mr. Chairman.

Mr. SYNAR. Why not? Will you provide it for the record?

Dr. PATRINOS. I will provide it for the record.

Mr. SYNAR. All right.

[The information follows:]

At this time, a cost comparison study has not been done. The Office of Energy Research will review the cost and revenue data submitted with the Project Definition Study reports when they are received and extrapolate existing cost and revenue data from laboratory construction and operations of radioisotope facilities in order to perform a cost comparison similar to what is called for under OMB Circular A–76. The Office of Energy Research will work within the Department and the Administration for formulate a plan for supporting the National Biomedical Tracer Facility based upon this data if the need for a National Biomedical Tracer Facility is confirmed by the Institute of Medicine.

Mr. SYNAR. Mr. White, let's go on with the NBTF just for a minute, it we could. I want to ask unanimous consent to enter into the record exhibit 17.

[Exhibit 17 can be found in the appendix.]

Mr. SYNAR. Now this exhibit is the supplemental information that applicants for the grants are required to obtain from Mr. Decker's office. It specifies that the parameters for the NBTF are those contained in the 1991 Society for Nuclear Medicine "Planning and Feasibility Report" in the proceedings of the 1992 Purdue workshop.

The question is what independent analysis of the specifications for the NBTF included in these two reports that you have before you did the Department of Energy perform before DOE's solicitation was sent out?

Mr. WHITE. I will have to defer to my colleague on this.

Mr. SYNAR. Dr. Patrinos.

Dr. PATRINOS. There was a Purdue University report, that looked at the issue of the NBTF.

Mr. SYNAR. We cited that, but what did you all do before DOE's solicitation? What review? What review of the Purdue study did you do?

Dr. PATRINOS. The review we have started is the review we have commissioned with the Institute of Medicine and the National Academy of Sciences that will examine the NBTF.

Mr. SYNAR. Now DOE contracted with the Institute of Medicine to do a study to actually assess the medical community's requirements. The estimated date for the completion of the Institute of Medicine study on that subject is October 1994, a date well after you issued the solicitation, correct?

Dr. PATRINOS. Before the project definition studies.

Mr. SYNAR. So you didn't do any independent review, did you?

Dr. PATRINOS. No, we did not.

Mr. SYNAR. According to the report of the 1992 Purdue workshop, no one from DOE even attended that meeting, did they?

Dr. PATRINOS. I am not aware of that, Mr. Chairman.

Mr. SYNAR. Any of you all know that? Well, according to the report, nobody was there. So you put out a RFP for $1.5 million in grants to define a $100 million facility, and DOE did not do any independent analysis of whether the objectives of the facility included in your own solicitation were correct, technically appropriate, or cost effective, right? Dr. Patrinos.

Dr. PATRINOS. I will have to go back and check and submit for the record whether we have consulted at least informally within the Department with respect to the NBTF.

Mr. SYNAR. All right. We will leave the record open for that search. All right.

[The information follows:]

The Department conducted an internal, informal review of the Purdue report which led us to question some of the findings in the report. For this reason we have requested the Institute of Medicine to conduct an independent evaluation of large proton accelerator produced radioisotope needs.

Mr. SYNAR. Paragraph 2 of the RFP, which we put in the record previously, identifies three missions for the Biomedical Tracer Facility. One, to produce isotopes for the nuclear medicine community; two, to conduct research for radioisotope production; and three, to provide opportunities for education and training in radioisotope production and they are amplified in the supplemental information packet, which we included in exhibit 17 and you have before you.

Does DOE really believe that conduct of research into radioisotope production and the education programs included in these studies are going to be commercially viable?

Dr. PATRINOS. We have at least heard one particular group that believes—that can operate the NBTF in a sustainable manner. We cannot independently——

Mr. SYNAR. On the basis of that, I heard something, you did the solicitation?

Dr. PATRINOS. That is the purpose why we have——

Mr. SYNAR. Who did you hear it from, Dr. Patrinos, who?

Dr. PATRINOS. The North Texas Research Institute that expressed—had a proposal.

Mr. SYNAR. How did they express? They call you up on the phone?

Dr. PATRINOS. No, they presented it before the Institute of Medicine's last meeting, about a month ago. And, in fact, to answer your previous question, that is one of the objectives of the Institute of Medicine study, to determine whether the NBTF can be operated in a sustainable manner.

Mr. SYNAR. So if the institute comes back in a year or so, Dr. Patrinos, with a report that identifies a set of requirements for isotopes that is different from the ones you put forward in your RFP, you will have already spent $1.5 million for studies that are not responsive to the institute's recommendations?

Dr. PATRINOS. Well, yes, but at the same time we will be able to craft a RFP——

Mr. SYNAR. Another one.

Dr. PATRINOS [continuing]. For the construction of the——

Mr. SYNAR. $1.5 million already out the door, and there will have to be another RFP, will there not?

Dr. PATRINOS. It is preferable to wait a year and do it right than to jump the gun and do it wrong.

Mr. SYNAR. That is not what you did here. What did you just do? I mean, I just walked you through jumping the gun.

Dr. PATRINOS. We issued a solicitation for the project definition study while the Institute of Medicine is deliberating many of the issues associated with the NBTF.

Mr. SYNAR. Exactly.

Dr. PATRINOS. We feel that the deliberations of the Institute of Medicine will help us both in terms——

Mr. SYNAR. But you didn't do an independent evaluation.

Dr. PATRINOS. The independent evaluation is the evaluation conducted by the Institute of Medicine.

Mr. SYNAR. But that is after the fact.

Dr. PATRINOS. It is not after the fact in terms of issuing an RFP for the construction of the NBTF, or proceeding perhaps with putting the NBTF at one of the DOE facilities if the deliberations——

Mr. SYNAR. It is after the fact of what you are figuring out what it is going to be.

Dr. PATRINOS. As I said before, it is preferable to wait a year and do it right than jump the gun.

Mr. SYNAR. All right. According to the RFP and to the business strategy plan, which was developed to support the RFP, DOE doesn't know if the production of the medical research isotopes is commercially viable either.

Again, DOE has initiated a process that simply assumed that all these missions were commercially viable, and you left no possibility for dealing with these needs in any other way, did you?

Dr. PATRINOS. That is not correct. We have not assumed that this is going to be a commercially viable operation. In fact, that is one of the charges we have given the Institute of Medicine.

Mr. SYNAR. All right. Mr. White——

Mr. WHITE. Yes.

Mr. SYNAR [continuing]. The notice states in column 1 on page 53198, look at it.

Mr. WHITE. Yes.

Mr. SYNAR. Let me read it to you. "If the data supports the need for the NBTF, as well as the fact that such a facility can be operated economically by the private sector, additional Congressional funding will be sought."

Does that mean that the Department has determined that if there is a need but that it cannot be economically operated by the private sector, that you will not ask for additional congressional funding to meet these needs?

Mr. WHITE. No, it does not.

Mr. SYNAR. Then why doesn't the notice say so? Why didn't you just lay it all out, all the options, as to how these needs would be met? Why didn't you initiate a process to define all the needs and all the options and how to meet them?

Mr. WHITE. The first thing that we did, Mr. Chairman, is to see if we can get some applications that do include an element of commercial independence.

Mr. SYNAR. To accomplish what?

Mr. WHITE. To——

Mr. SYNAR. What is it—you are getting proposals for what?

Mr. WHITE. For the facility definition, the National Biomedical Tracer Facility definition study.

Mr. SYNAR. What facility? What is this facility? What is it going to do?

Mr. WHITE. I will be as clear as I can. We want to rely on people in the private sector, including people with public health expertise and others, to help tell us what a facility would look like that would be commercially viable. We are not claiming that we have all the expertise within the Department of Energy.

Mr. SYNAR. But that is not the process, Mr. White, that you have set up. That is not the process we have just walked through here.

Mr. WHITE. With due respect, Mr. Chairman, I believe that the notice that we have here within the Federal Register is designed to seek the expertise of people——

Mr. SYNAR. Let's talk about that expertise. And I don't mean to interrupt you.

Mr. WHITE. Yes.

Mr. SYNAR. But even if Mr. Decker didn't want to allow the DOE labs to compete for the NBTF, DOE can still use their expertise, could they not?

Mr. WHITE. Yes.

Mr. SYNAR. Now Brookhaven has all the expertise that your solicitation says that you are looking for. In fact, they have probably more expertise in doing this than anybody in the country. Why did you cut them out of the process of providing the Department and Congress with information on the need for this facility?

Mr. WHITE. I hope and I would expect that nobody has been cut out of the process.

Mr. SYNAR. The solicitation cuts them out. We asked the people at Brookhaven to tell us what role they had in the developing of that solicitation. And you know what they told us? They told us that they had no role whatsoever. Why not?

Mr. WHITE. I will defer to my colleague, but—on that.

Dr. PATRINOS. Mr. Chairman, the OMB Circular A–76 that you quoted earlier forces us to not compete, the national laboratories, with private sector.

Mr. SYNAR. But you can still use the expertise of Brookhaven.

Dr. PATRINOS. We certainly used the expertise——

Mr. SYNAR. I just told you we asked them that. They said they had absolutely nothing to do with it, they were never asked.

Dr. PATRINOS. Let me first seek a clarification about what is exactly that they were not asked about?

Mr. SYNAR. They played no role in developing the solicitation.

Dr. PATRINOS. That is not true, Mr. Chairman. I came from Brookhaven. I have a lot of friends at Brookhaven National Laboratory, and I have spoken with them over the last 6 months, on the issues.

Mr. SYNAR. Who did you talk to, for the record, at Brookhaven?

Dr. PATRINOS. I spoke with Dr. Petrackis.

Mr. SYNAR. In what role?

Dr. PATRINOS. Pardon me?

Mr. SYNAR. What formal role did those folks have?

Dr. PATRINOS. He is one of the associate directors, I understand, for the Applied Science Division.

Mr. SYNAR. Who else did you talk to?

Dr. PATRINOS. He is the person I spoke to. I also spoke with other people that were peripherally involved, perhaps, with the matter. So——

Mr. SYNAR. Let me ask you—go ahead. All right. You do admit that Brookhaven cannot compete in this solicitation?

Dr. PATRINOS. At this stage, yes. If you will allow me to walk you through the process of——

Mr. SYNAR. Dr. Patrinos, we did that a minute ago, and I got so lost I think you lost the audience.

Let me ask unanimous consent exhibit 18 be made part of the record.

[Exhibit 18 can be found in the appendix.]

Mr. SYNAR. Mr. White, this is the business strategy plan drafted for Dr. Decker to guide the preparation for the request for proposals we have been discussing.

The report on page 2 and 3 states that the data presented indicates that 98 percent or more of the U.S. requirements for isotopes for nuclear medicine applications could be met by the planned upgrade of the Brookhaven Linac Isotope Production [BLIP] facility alone.

It goes on to say that the business strategy group questions the prudence of pursuing construction of a new $100 million facility to satisfy approximately a mere 2 percent of the isotope requirements not satisfied by the BLIP upgrade. The group went on to presume that the new $100 million facility would be built anyway.

Now, Mr. White, in light of this plan and all the work that you support at these labs, didn't it occur to DOE that your facilities might be capable of meeting most, if not all, of the missions of the NBTF or, at least, that you could investigate that option?

Mr. WHITE. Yes, it did occur to us. And, yes, I know based on questioning this morning that we did investigate that option, including options at Oak Ridge for the production of those, the stable isotopes. What format that input took, I will defer to my colleague on.

Mr. SYNAR. Where is that analysis, Mr. White. We don't have that.

Mr. WHITE. Where is the written analysis?

Mr. SYNAR. Yes, where is the analysis of all that?

Mr. WHITE. Well, I do not keep the files.

Mr. SYNAR. Dr. Patrinos, where is the analysis?

Dr. PATRINOS. The analysis of which? Could you please clarify?

Mr. WHITE. The analysis——

Mr. SYNAR. Considering Brookhaven, that we just showed you, where is that analysis? Since you were in consultation, where is the analysis?

Dr. PATRINOS. Well, I can provide for the record a lot of the documentation that deals with the upgrade of the BLIP facility, which is in fact a stopgap measure to meet the needs of accelerator-produced isotopes. This is something that is, in fact, in our fiscal 1994 budget.

[The information can be found in the appendix.]

Mr. SYNAR. Are you funding the upgrade of BLIP, correct?

Dr. PATRINOS. Yes.

Mr. SYNAR. Yet you designed a process that doesn't consider the capabilities of Brookhaven for the NBTF, haven't you? That it doesn't even contemplate allowing them.

Dr. PATRINOS. That is not correct, Mr. Chairman.

Mr. SYNAR. I can read the solicitation. I may not be able to do a lot of things, but they are out.

Dr. PATRINOS. That solicitation is not for the construction of the NBTF, but for the project definition study.

Mr. SYNAR. We understand that.

Dr. PATRINOS. Mr. Chairman, allow me to finish.

Mr. SYNAR. Go on.

Dr. PATRINOS. If the Institute of Medicine determines and tells us that the NBTF cannot be built and operated in a sustainable manner, it will probably behoove us to consider competing it among the national laboratories. And certainly——

Mr. SYNAR. Dr. Patrinos, stop. Now listen, you did this a minute ago, and you confused me, and I thought you misspoke. You got a solicitation out here, $1.5 million, and yet the information based upon the medical needs is coming years late. Now where is this cart? Is it before the horse or behind the horse? Just what is wrong with this picture?

Dr. PATRINOS. I think it is clearly one case where the horse and the cart are side-by-side. But at the same time, Mr. Chairman, it would be preferable to do this——

Mr. SYNAR. The solicitation is now, and the report is not until October 1994; is that correct? That is not side-by-side. How does that go side-by-side? The solicitation is right now. The report is not until October 1994.

Dr. PATRINOS. But this solicitation is not for building the NBTF. This is for the project definition study [PDS]. The winner—if there is a winner——

Mr. SYNAR. That is the point. That is the point.

Dr. PATRINOS. Exactly, that is the point. The PDS grantees may not necessarily build and operate the NBTF. This is a project definition study solicitation. The output is not a facility. It is a report addressing a number of issues including refining the design, including addressing environmental issues, including examining the management and the education aspects.

Mr. SYNAR. But the bottom line is you have exempted the labs.

Dr. PATRINOS. I have not exempted the labs, Mr. Chairman. We have to do that; we have to do due process.

Mr. SYNAR. Can they compete or not, Dr. Patrinos.

Dr. PATRINOS. Excuse me?

Mr. SYNAR. Can they compete or not?

Dr. PATRINOS. They cannot compete in this, I repeat. But they can certainly complete if——

Mr. SYNAR. They cannot compete, but they can certainly compete, that is a good one, all in one sentence.

Dr. PATRINOS. Allow me to finish the sentence, Mr. Chairman. They can certainly compete if the institute tells us that the private sector cannot operate it in a sustainable manner. We are bound by our rules and regulations, Mr. Chairman.

Mr. SYNAR. I would like to ask unanimous consent to make exhibit 19 part of the record.

[Exhibit 19 can be found in the appendix.]

Mr. SYNAR. This is a letter from Brookhaven National Laboratory. This is responding to a series of questions from this subcommittee concerning BLIP, and the upgrade, the potential for further upgrades.

Mr. White, I recognize that you may not have had an opportunity to see this document, but it indicates that the BLIP upgrade will substantially increase BLIP's capability and that additional upgrades could be achieved at minimal cost. For example, for an additional $10.5 million, the "beam current" can essentially be doubled over that achieved by the BLIP upgrade, which in itself would be more than double the existing current. And additional upgrades may be possible.

Your process doesn't provide a mechanism for even considering those alternatives, does it?

Mr. WHITE. I disagree, and I will tell you why, but I think that I have drawn a conclusion that I hope would satisfy the chairman's concern.

We have here—obviously Brookhaven has some ideas concerning what a project definition would look like. We have also sought some ideas outside of Brookhaven concerning what the project definition should look like. Brookhaven says in the letter to you, I note, Mr. Chairman, that for $350,000 it is interested in developing an NBTF proposal. I don't know whether that—I am at, Mr. Chairman, on page 4, 3c.

Mr. SYNAR. I got it. I am reading it right here.

Mr. WHITE. And it——

Mr. SYNAR. Is that going to come out of Dr. Patrinos' budget?

Mr. WHITE. Well, my conclusion would be that I think that we ought to use the expertise which is in Brookhaven and we will find the money to do it. So that we can, instead of having just the five, we will have six, including Brookhaven, who has given this a lot of thought.

Mr. SYNAR. All right. Mr. White, we have discussed the Department of Energy's physical facilities and capabilities to produce isotopes. I want to turn to the institutional structure that is now in place and its problems.

First, notwithstanding the requirements of Public Law 101–101 that your isotope programs be operated at full cost recovery basis, in fact some isotopes, such as some of the transuranic isotopes and medical research isotopes, continue to be funded by your research program outside that revolving fund; is that not correct?

Mr. WHITE. Yes.

Mr. SYNAR. Second, now Public Law 101–101 set up a full cost recovery revolving fund. As a result, DOE has had to increase prices for research isotopes to the point where some researchers have actually abandoned some areas of the research. DOE is selling off the research materials collection. DOE has spent millions of dollars trying to develop products, such as the moly-99 that will generate some high revenues, but the program isn't financially solvent, is it?

Mr. WHITE. That is correct.

Mr. SYNAR. In fact, according to the CFO Act audit that we talked about earlier in some panels this morning, completed by your inspector general in June, during the first 3 years of operation, that program sustained cumulative losses of about $12.5 million; is that correct?

Mr. WHITE. I believe so.

Mr. SYNAR. Now, in fiscal year 1992, DOE received authorization to borrow $8.5 million from the Treasury and another $5 million in borrowing authority for 1993 and this year you have requested and received a straight appropriations of about $3.9 million for fiscal year 1994, yet there is no indication that we can find that these infusions of cash have been or will be enough to keep the program financially solvent, is there?

Mr. WHITE. I think that is right.

Mr. SYNAR. DOE also has a policy dating from 1965 that you will not compete with domestic suppliers. The Atomic Energy Act, on the other hand, simply precludes you from pricing your products in a way that would discourage alternative sources of supply. And on October 25, we wrote to DOE and the U.S. Trade Representative asking you to explain the Department of Energy's policy on competition with domestic suppliers. As you know, we received that response this morning.

We also asked you to describe for us how these limitations on competition were consistent with DOE's previous decision to compete against a Canadian supplier, Nordion. We thought that request was pretty straightforward.

It is now, as you know, December 6. Can you tell us why the administration has been unable to respond to our questions on this subject for 6 weeks, and just exactly how long would it have taken if we had not scheduled you to testify here today?

Mr. WHITE. There is no excuse for delay in correspondence of that length from us, and I don't know what role the concurrence of the USTR had to do with it, but the Secretary and I are not satisfied with the turnaround that we are giving to requests like this from Members of Congress and we address that usually twice a week at a meeting.

Mr. SYNAR. I want to ask unanimous consent that exhibit 21, Secretary O'Leary's letter dated December 3, 1993, and delivered to the subcommittee this morning be made part of the record.

[Exhibit 21 can be found in the appendix.]

Mr. SYNAR. According to your response, the DOE essentially employs, "a reasonably available test." If isotopes are reasonably available in a commercial market, DOE won't compete; is that correct?

Mr. WHITE. Correct.

Mr. SYNAR. According to your response, you believe that because of the threat of supply disruptions of medical isotopes involving AECL and Nordion, this supply does not meet the "reasonably available" test. Therefore the Department's efforts to develop moly-99 are consistent with that existing policy, correct?

Mr. WHITE. Correct.

Mr. SYNAR. Is that going to be the policy under this administration? Will this be continued?

Mr. WHITE. Concerning the moly-99?

Mr. SYNAR. The "reasonable availability."

Mr. WHITE. Yes.

Mr. SYNAR. And the tests for Canadian supplies is whether they are available in the United States market. If they are, they are treated essentially as the same as domestic supplies; is that correct?

Mr. WHITE. I would say that that is not entirely correct, that this one source is outside the United States, I know that in my own mind, in thinking of this, as well as in the Secretary's, this is a factor in determining the security of that source of supply. So——

Mr. SYNAR. Isn't that what is in the letter? The Canadian-produced radioisotopes are not accorded special treatment under the United States Canadian Free Trade Agreement under NAFTA. All these provisions relating to trading goods under these agreements apply.

Generally speaking, under these agreements, Canadian-produced radioisotopes are to be treated no differently than United States-produced isotopes. It is in your letter of today—I mean delivered to me today.

Mr. WHITE. Yes. I think you are looking at the question concerning the treatment under the United States-Canadian Trade Agreement and NAFTA.

Mr. SYNAR. Right.

Mr. WHITE. And I was talking about the question of whether or not our determination of reasonable availability took into account the fact that a supply was from a source outside the United States, and that is a factor that I know that we have been concerned with in this moly-99 decision.

I think the fact that if there is a single source, say, and if it was in Russia——

Mr. SYNAR. I am about to get into that. One of your major competitors today for stable isotopes is the Soviet Union. In fact, the former Soviet Union is the only other source for a number of these isotopes. Is it the Department's opinion, based upon the economic and political situation in the former Soviet Union, that the supply of stable isotopes is "reasonably available"?

Mr. WHITE. In making a particular capital expenditure, we would have to look at the particular fact, but I will say that it would be a—if the only source was in Russia, that that would be a very significant factor in determining whether or not there was reasonable availability.

Mr. SYNAR. So DOE is going to make the same commitment to maintain a source of supply for stable isotopes that it is making for medical isotopes, right?

Mr. WHITE. For research isotopes?

Mr. SYNAR. Right.

Mr. WHITE. Yes.

Mr. SYNAR. As you know, the suppliers in the former Soviet Union have an enormous incentive to sell it for hard currency.

Mr. WHITE. Right.

Mr. SYNAR. It is not clear what their cost of production is or the level of continued government support or level of political stability, and we heard earlier that one of DOE's major medical customers is willing to pay a premium to keep DOE in business.

How is DOE going to compete with these suppliers?

Mr. WHITE. These suppliers in the Soviet?

Mr. SYNAR. Yes.

Mr. WHITE. We will compete, as we have in the past, which in some cases has required government subsidies, and as I stated, we need to make what changes may be appropriate in the revolving fund concept to do so. Mr. Chairman, I will also say, because we will be dealing, I hope, with these matters for some time, that if there was a case in which there was a huge capital expenditure required in the United States and there was a foreign source that seemed reasonably secure, that is something also that we would need to take into account.

Mr. SYNAR. The record shows that notwithstanding the intent of Public Law 101–101 that this activity be operated in a for-profit business, that the bottom line is that DOE has not done so.

A variety of examples of financial and institutional problems are detailed in the Arthur Andersen study with which you are familiar, as well as the IG's recent audit and I want to get into this, if I could.

First, Mr. White, your testimony says that you have been reorganizing the Isotope Production and Distribution Program and that this will be complete in the middle of January.

Mr. WHITE. Yes.

Mr. SYNAR. What is it you are reorganizing? What changes other than removing an individual who has been trying to run the program have you already made that will be done on January 15, 1994?

Mr. WHITE. We will be appointing somebody with principal responsibility in marketing and we will, for I would say most of the recommendations set forth in the Peat Marwick report, as well as several in the Arthur Andersen report, be making changes in the program administration which are consistent with those two accounting reports. I will prepare and submit to you point-by-point in each of those two reports, the specific actions which are being taken in response to the criticisms and suggestions.

Mr. SYNAR. We are talking about three people running a $15 million a year business with 1,000 customers and 7 production and distribution sites.

It is pretty hard for this subcommittee to believe that those folks have been able to run it at all wouldn't you agree with that, Mr. White.

Mr. WHITE. I don't know actually what the number of government employees is, but——

Mr. SYNAR. Three.

Mr. WHITE. Three?

Mr. SYNAR. Yes.

Mr. WHITE. I have—let me consult.

Mr. SYNAR. Mr. Lowe, how many people work down there?

Mr. WHITE. I believe there are six.

Mr. LOWE. Six.

Mr. SYNAR. Six running a $15 million a year, thousands of customers, seven production and distribution sites. Pretty good job for six people.

Mr. WHITE. I agree.

Mr. SYNAR. Mr. Lowe, how does your program market its products and how many full-time marketing representatives work for you?

Mr. LOWE. There are, at this time, no full-time Federal employees as marketing representatives. We have relied on the National Laboratories to do the marketing function. That marketing function can be best characterized as taking orders, not a real business-oriented marketing function at this time.

Mr. SYNAR. Could you contract marketing services?

Mr. LOWE. We have not contracted.

Mr. SYNAR. Could you?

Mr. LOWE. I think we could, yes.

Mr. SYNAR. And while the DOE consolidated the distribution of isotopes, the program doesn't really have a controller over the production or costs, does it, Mr. Lowe?

Mr. LOWE. It does not.

Mr. SYNAR. What control do you have over your production schedules?

Mr. LOWE. The production schedules are negotiated with the individual facilities based on not only the needs of the isotope program, but also the needs of the primary——

Mr. SYNAR. Same thing for costs, too?

Mr. LOWE. Yes, costs the same way.

Mr. SYNAR. But you have no direct control?

Mr. LOWE. No direct control.

Mr. SYNAR. Now, because it doesn't have direct control over production, the Department of Energy is often not a reliable supplier in the markets that demand—as you heard from two panels this morning—reliability. This is especially true for the reactor produced radioisotopes such as iridium. Some of your iridium customers are about to go out of business.

What steps are you going to take to improve the reliability of reactor-produced isotopes?

Mr. LOWE. There are two potential sources of producing the products these people need. We are looking at alternate ways of getting the product from the reactor to these people.

Further detail eludes me at this point, but we are investigating those alternate sources.

Mr. BROLIN. I may be able to——

Mr. SYNAR. That is it?

Mr. BROLIN. I may be able to help, Mr. Chairman.

Mr. SYNAR. All right.

Mr. BROLIN. There are a couple of things that we have done to improve the reliability of supply of iridium-192. One is to upgrade the capability and the safety of the hot cells at the test reactor area in Idaho where the iridium-192 is produced in the Advanced Test Reactor. That upgrade has been completed and actually they started operating again last summer and producing iridium-192.

We have also developed a backup source of iridium-192 at the HFIR reactor at Oak Ridge. However, the use of the hot cells there has proven to be, frankly, too expensive to meet the market needs and, therefore, we are investigating and expect to make a decision shortly as to where we can process the iridium-192 after it comes out of the HFIR reactor.

Mr. SYNAR. Mr. Lowe, your program has to absorb literally millions of dollars of additional costs because of the way in which the Department of Energy levies overhead charges on the program. In fact, the Arthur Andersen analysis indicates that this one change alone could allow the isotope program to break even.

Now, Mr. White, what is wrong with assessing the overhead charges for the work done by Mr. Lowe's program based upon incremental cost of performing work for the program as proposed by the Arthur Andersen study?

Mr. WHITE. I believe that an evaluation of the incremental costs will be important in trying to assess whether or not to produce a particular type of isotope. I also think it is important, though, that in trying to compare the relative costs of the various programs within the Department of Energy, we have some kind of common ground of cost allocations, so that if we compare an energy research program of a particular nature to a nuclear energy program——

Mr. SYNAR. Not to interrupt you again, but that is not the question. The question is what you charge the isotope program. What do you charge?

Mr. WHITE. Our pricing is based on what we can recover, not based on what our cost is. We do have some statutory—this revolving fund idea does embody the idea of recovering the costs on an overall program basis, but as we have both discussed, that has not worked in the past and because of the priority that we have given this program, we have priced below what our fully allocated cost is and we have had to seek borrowings as a result of that. So our cost allocation has not and should not, based on the principles I have articulated, influence what the pricing actually is.

Mr. SYNAR. It is not what you charge; it is what DOE charges the isotope program, right?

Mr. WHITE. What it allocates to the isotope program, correct.

Mr. SYNAR. Now, the overhead charges that DOE charges the isotope program is the problem, is it not?

Mr. WHITE. I don't think it is a problem unless that led us to a particular decision to discontinue the production of a certain——

Mr. SYNAR. Isn't that what Arthur Andersen said in their study, that the failure to base it on incremental costs is the problem, that that one change could make it break even.

Mr. WHITE. Well, the significance of what they are saying is that if you wanted to make the program consistent with the revolving fund legislation, you should allocate only incremental costs to this particular program, and I am telling you, my answer to you, Mr. Chairman, is that we have gone beyond the revolving fund concept of this program and are seeking borrowings. So the cost allocation procedures have not so far resulted in the discontinuation of the program.

Moreover, I am saying that it would be a bad managerial precedent for the Department of Energy to remove the cost allocation system that is currently in effect, because then we would not be able to compare the fully allocated costs of different programs, program-to-program. So, if we report to you and the OMB and others, we want to be able to compare apples to apples when we are looking at different programs, be it the isotope program or basic science programs.

That is why I think that the Arthur Andersen conclusion concerning cost allocation, while it might be a guide to whether or not at some point we should discontinue the production of a particular isotope, because it is just too costly, doesn't have any immediate operational impact so long as we are not simply closing the doors, once we hit the limit of the revolving fund.

Mr. SYNAR. We are trying to pin down that answer. Is it the fact that you are not in the revolving fund any longer means that you don't have to worry about overhead?

Mr. WHITE. No, that is not what it means. It means that the failure to use an exceptional cost allocation process in this program, which would make it different from every other Department program, does not have operational consequences for the program. Then I am further suggesting that if we did make an exception for this program, that that would be poor management of the Department as a whole.

I think it is important for the purposes of our program management and oversight that we do allocate overhead costs between programs based upon the relative use, rather than having one program claim that all of its overhead should be allocated to another program, because that program would have used the facility anyway.

Mr. SYNAR. Mr. Berick, why don't you go at it. I don't think you are answering what we need to know here.

Mr. WHITE. I apologize for that. I am trying the best I can.

Mr. BERICK. I guess there are two questions. One is, in the future.

Mr. WHITE. Yes.

Mr. BERICK. The extent to which the cost structure that the program has now been forced to bear, as identified by Arthur Andersen, as being the difference between being solvent and being insolvent, is going to be borne by the program.

The other question is the one that Arthur Andersen raises which is whether or not this, under the current structure, is an appropriate way of levying overhead charges on an operation that is, in fact, different from all other Departmental activities in that it has to operate as a profitmaking entity in the marketplace.

So I appreciate the point you are making, which is that it is an exception and once you make an exception, it is hard to run the Department. Arthur Andersen comes to the conclusion that because this is so unique, that it can simply not continue to compete under that cost structure. So that is the first part.

And the second part is, to the extent that you are going to change the way we do business, how are overhead charges going to be dealt with so that, in fact, the new entity, the new mechanism, still isn't swamped by overhead charges?

Mr. WHITE. Good point, and I am just telling you that I will make it as plain as I can. We have this revolving fund concept, which I said doesn't work, that was based on some misconception that we were going to have these things that were going to be on a stand-alone basis and Arthur Andersen is saying, well, look, if you make—one way you could do it is to tinker around with your cost allocation to make it come in under that threshold.

My point is, let's be honest about it. Let's not tinker with your normal cost allocation. Let's say what the problem is. The problem is that the revenues are not going to support some important social functions that are necessary for medical and research purposes, rather than tinker with the cost allocation mechanism, because once we tinkered with the cost allocation mechanism on one program, we would have every program in the Department claiming that it was in a sense unique.

I mean it was unique because we needed to avoid proliferation of nuclear weapons. We needed—you see what I am saying? So that is my point. I think that the thrust of the Arthur Andersen report, that is, this is broken unless you improve your cost allocation or change it, I agree with.

The remedy, I think, is to come to this body with some, you know, amendment to the revolving fund formula.

Dr. KNUTH. I wonder if I could add to that, at the risk of raising my head again, how we plan to operate Omega West when NE (Office of Nuclear Energy) was going to use it part time. We had agreed that since we needed that reactor 1½ years ago for defense purposes, we would pay for the operations for one shift per day operation, and if they needed to go round the clock, that we would only be seeking reimbursement for the differential cost to put on the added shifts.

Unfortunately, then the decision was made by this administration to downsize the weapons program and we basically shut down and put the K-Reactor in standby status. We have given up Rocky Flats. We are moving out of Pinellas. We are moving out of Mound. We saw that we no longer had any programmatic reason since we are not making any more nuclear weapons, new designs, or have any use whatsoever in Defense Programs for Omega West.

We, at that point said to NE, if you want the reactor, it is yours since we no longer have a programmatic need for that reactor. Therefore, at the end of this fiscal year, we are stopping all funding for the reactor and in the meantime, as I said before, planned to shut it down, but made no decision that it could not be brought back on line if someone else wanted to pick up the reactor for other purposes, such as isotope production.

So we in DP (Office of Defense Programs) had planned to coordinate with NE an incremental costing for Omega West originally, but when we got to the point where we are now and had no need for it, the concept changed such that NE or whoever runs it for isotope production would have to bear the full cost for it.

Mr. SYNAR. Mr. Clinger.

Mr. CLINGER. Thank you, Mr. Chairman. I just have one additional question and then a request that the record might be kept open for questions I might submit.

Mr. SYNAR. Absolutely. Unanimous consent.

Mr. CLINGER. Just on this question of reliability of supply, which is, I think, a critical issue here, and some of your customers or potential customers, existing or future customers raise a couple of concerns about the reliability of the Department as a supplier.

No. 1, that it is not available as a source of supply 365 days a year, whereas there is often a need that exists or can exist over a 365-day period.

Second, that the Department is unable or unwilling or I am not sure why, to enter into anything but very short-term contracts. In other words, that there is no sort of stability of price involved here, whereas other competitors are willing to enter into longer term contracts, say 5 to 10 years, and that that gives them more assurance that they have control on what the prices are going to be, and finally, that the Department has been unwilling to have any penalties assessed to them, in other words, for nonperformance or inability to provide.

There is really no teeth in it. If you fail to come through, there is no penalty involved, and that again raises questions in the minds of some of your potential customers that you are just not a reliable supplier.

Mr. WHITE. Correct, and one of the recommendations of the Arthur Andersen report is at paragraph 7, page 5 where they recommend we take steps to improve the reliability of the delivery. We are taking steps to try to obtain some firm commitments from the contractors with the DOE who do operate our sources of supply to come up with some, for example, secure pricing well into the future. And if we get that kind of pricing, then we would have the ability to, with more prudence, enter into a longer term contract where that is required to meet competition.

Of course, all of this has a cost. That is to say that, if you want to pin somebody down to a fixed price, then that person may very well demand some premium to take into account the variation which may occur within their own cost in order to provide the particular isotope, and what we are going to be trying to balance is to try to keep the cost of this program as low as we can consistent with providing the isotope, and sometimes it is my impression now in reviewing it that that does make us a little frayed around the edges, but it is not because people have deliberately wanted to sabotage the source of supply.

It is because we have been operating in an environment in which we know we are mandated by Congress, in order to try to make the revenues equal the costs, and that is the reform that I think needs to be done if we are going to put this on a reliable basis. It is that reform of the revolving fund that we are going to be looking at to upgrade some of the quality of service.

Mr. CLINGER. I think if you are going to operate at the lowest possible cost, there is a fine line here. It gets to the point where it is so low that you become a totally unattractive potential supplier, then you have no customers at all.

Mr. WHITE. That is exactly correct. And you see it with businesses that are, shall I say, strapped with cash-flow, as well as this program. I mean, that is my benefit coming in here and looking at some of the reasons why we have some of these problems is because of that mandate. People are trying to scramble to keep the cost as low as possible.

Mr. CLINGER. We have got to keep in mind here the overall objective of this which is to have customers. You have got to have a pretty sure ability to fix the cost and also that there be a reliability of supply.

Mr. WHITE. No question.

Mr. CLINGER. OK. Thank you, Mr. Chairman.

Mr. SYNAR. Thank you. Before we conclude, let me correct the record. We need to add two additional pages to exhibit 15 which should consist of 3 pages: That is pages 13, 14, and 15.

Mr. White, since Friday when you turned in your testimony, you all have been pretty damn busy down there. Let me tell you what you have done.

You have made major decisions to get rid of the revolving fund, keep Omega West, close Fast Flux and make this program a new priority. I hope those decisions were not done just to get us off your back for another year. I hope they were well thought out. I am worried. I have never seen so much activity in a weekend in my life. Our problem is that we held a hearing in August 1992. We were told that this just wasn't a high priority. DOE has been hell bent to prove over the last year that it hasn't been a high priority.

Now, you all had a lot of vigor when you were supporting this Superconductor/Supercollider at billions of dollars because you wanted to invest in the scientific infrastructure. I don't think it is any secret, as we begin this next session of Congress, that health care is the President's top priority, as well as Congress'.

Part of delivering good health care is this program, because without it we cannot do the kinds of research and day-to-day medicine that the Nation demands. I have only known you for a couple of months. Your commitment today is that you want to start to make this a new priority. I take you at your word.

But I have got to tell you, you have been there a number of months and you have seen how your Department literally scrambled over the weekend. That is not a good indication of commitment.

We are worried. And the reason we have gone through this long excruciating hearing today is to try to point out to you and everybody else that we are dead serious about this. I don't want to have to come back here in another year. So I hope that this has been instructive to you and I do hope all these decisions that have happened over the weekend are good decisions because we don't have any analysis or understanding of how some of them were made.

This concludes this hearing. We look forward to working with you and your people on this matter as we proceed for the country on the isotope issue.

[Whereupon, at 3:47 p.m., the subcommittee adjourned, to reconvene subject to the call of the Chair.]

APPENDIX

MATERIAL SUBMITTED FOR THE HEARING RECORD

EXHIBIT 1

Canadian Embassy

Ambassade du Canada

NOV 16 1993

501 Pennsylvania Ave., N.W.
Washington, D.C. 20001

November 15, 1993

The Honourable Mike Synar
Chairman
Subcommittee on Environment,
Energy and Natural Resources
B371B Rayburn House Office Building
Washington, D.C. 20515-6145

Dear Mr. Chairman,

Following your letter of October 26, I am pleased to provide you with the attached information on the status of isotope production activities in Canada.

As you are aware, MDS Health Group Ltd. - the majority owner of Nordion International Inc. - and AECL are engaged in private arbitration and legal proceedings to resolve contractual issues between them. AECL has indicated that it will use its best efforts to ensure continuity of molybdenum production using the NRU reactor, which is operating well.

You should note also that Nordion International, as prime supplier, is the appropriate commercial organization to provide information on the supply of radioisotopes. AECL, as a sub-contractor to Nordion, is engaged in a strictly commercial undertaking and not as an agency of the Canadian government.

If you or your staff have any more questions, please contact Guy Saint-Jacques of my staff at (202)682-7741.

Yours sincerely,

John de Chastelain
Ambassador

Attachments

Responses to questions raised by Representative Mike Synar, Chairman of the U.S. House of Representative's Subcommittee on Environment, Energy and Natural Resources (Letter to Ambassador de Chastelain, October 26, 1993).

1) It is our understanding that AECL is currently operating a single isotope production reactor (the NRU reactor) and has proceeded to begin decommissioning of its "standby" reactor (the NRX reactor). Please describe the status of AECL's isotope production reactors.

> The NRX reactor was shutdown in January 1992 for emergency repairs and was not restarted. It was decided in March 1993 to shut the reactor down permanently for safety and regulatory reasons. The early stages of decommissioning have been completed.
>
> The NRU reactor continues to be AECL's primary isotope production reactor and AECL will use its best efforts to ensure continuity of molybdenum production. The reactor is operating well.

2a) We also understand that AECL is currently constructing a new reactor dedicated to isotope production (the Maple-X reactor). We have heard that technical difficulties and regulatory concerns involving the coolant system design and potential for the reactor to have a positive reactivity coefficient under certain reactor conditions have prompted a temporary halt in construction. Please describe the construction, technical and regulatory status of the Maple-X reactor, including plans for resolving technical issues and the expected dates of completion and operation.

> The Atomic Energy Control Board - Canada's nuclear regulatory authority - has recently completed its review of the Maple-X design and predicted behaviour under normal and postulated accident conditions. Based on this review, the Staff of the AECB have concluded that the reactor design satisfies regulatory requirements and have recommended that a construction license be granted.
>
> Nordion International Inc. and AECL are involved in a private arbitration to resolve contractual issues between them. In addition, on October 25, 1993 MDS Health Group - the majority owner of Nordion - filed a Statement of Claim in the Ontario Court against the Government of Canada, the Canada Development Investment Corporation, and AECL. These matters were made public on October 25th through a media release issued by the MDS Health Group.

.../2

In view of the arbitration and legal proceedings and absence of a commercial justification, AECL has notified Nordion that it is not proceeding with the construction of Maple-X. The future course of events will be determined by the arbitration and legal proceedings.

2b) Will the NRU reactor be retained in standby to support continued production after Maple-X is operational?

It is AECL's intention to continue to operate the NRU as the primary isotope production reactor. Issues now in arbitration between AECL and Nordion will determine the future availability of the Maple-X reactor. These issues will not be resolved until mid-1994, at the earliest.

2c) What quantities of isotopes of current commercial interest is Maple-X expected to produce and how does this capability compare with current quantities produced utilising the NRU reactor?

The Maple-X reactor has been designed to meet the following annual isotope quantities at reactor exit: up to 5 million curies of molybdenum-99, 4 thousand curies of iodine-125, 40 thousand curies of iodine-131, and 300 thousand curies of xenon-133. NRU has the capability to meet these levels today.

3) Please describe what percentage of these AECL reactors is utilised for production for Nordion, how construction and operation of the AECL reactors are financed and the contractual/financial relationship between AECL and Nordion.

- The NRU reactor is AECL's primary isotope production reactor, as well as the primary research reactor. NRU is operated on full-time basis for research purposes, while accommodating continuity of isotope production. Isotopes are produced on a fully commercial basis.

Maple-X would be fully dedicated to isotope production and its capital and operating costs must be recovered from isotope sales revenues.

The contractual/financial relationship between AECL and Nordion is governed by a commercial contract, the details of which are a private matter.

4) Please describe the extent to which AECL or other governmental entities provide reactor-produced and accelerator-produced isotopes for non-commercial research purposes.

AECL produces only reactor-based isotopes for commercial purposes. All of these isotopes are produced for Nordion under an exclusive supply contract.

EXHIBIT 2
Page 5

FOCUS - 4 OF 26 STORIES

Copyright 1993 Canada NewsWire Ltd.
Canada NewsWire

October 25, 1993, Monday

SECTION: Financial News

DISTRIBUTION: Attention Business Editors

LENGTH: 466 words

HEADLINE: MDS HEALTH GROUP LIMITED

DATELINE: TORONTO, Oct. 25

BODY

MDS Health Group Limited ("MDS") today announced that its 83 per cent owned subsidiary Nordion International Inc., ("Nordion"), has entered into arbitration proceedings with one of its major suppliers of isotopes, Atomic Energy of Canada Limited ("AECL"), a Federal Crown Corporation.

AECL produces isotopes for Nordion from two research reactors located in Chalk River, Ontario. In March 1993, Nordion was informed by AECL that one of the reactors which had been temporarily shut down for repairs, would not be restarted. The existing contract between the two companies requires AECL to have an operational backup isotope reactor. AECL claims that the inability to recommission the backup reactor is "force majeure", namely caused by circumstances it was unable to prevent. AECL also claims that this situation entitles it to terminate its contract with Nordion.

In the arbitration proceedings provided for in the contract between Nordion and AECL, Nordion will contend that the shutdown of the backup reactor was not "force majeure" and, in any event does not give AECL any rights to terminate the contract.

AECL has advised Nordion that it will continue to supply isotopes until the arbitration proceedings are complete and if a determination is made in Nordion's favour, AECL will continue to provide isotopes in accordance with the terms of the existing contract. Otherwise, it will claim payment from September 27, 1993 onwards, on a reasonable basis reflecting its costs for isotopes sold to Nordion in the future.

In a separate action filed in the Ontario Court (General Division) today, MDS has commenced proceedings against AECL, the Canada Development Investment Corporation ("CDIC") and the Government of Canada, seeking a ruling that AECL has an obligation to complete the building of a new isotope reactor. The timing of this judicial action was necessitated because of certain contractual time limitations governing claims against the Crown in this instance. Alternate relief claimed in the action includes the rescinding of the original purchase and damages of $ 300 million. Nordion will continue to work with AECL, CDIC and representatives of the Federal Government to resolve, outside of the legal process, the pricing and capital funding issues which are the basis of the dispute.

On November 1, 1991, MDS acquired Nordion for $ 165 million from the Government of Canada and CDIC in a competitive bidding process. A significant asset of Nordion is the long term supply contract for isotopes with AECL which has a remaining term of 18 years.

MDS is Canada's largest diversified health care company. Nordion is a leading worldwide provider of isotope products which are used in a variety of medical diagnostic applications.

For further information: Ronald H. Yamada, Senior Vice-President, New Technologies & Corporate Affairs (416) 675-7661 Ext. 4224

LANGUAGE: ENGLISH

LOAD-DATE-MDC: October 25, 1993

GLOBE AND MAIL - DOCUMENT 1 OF 1 -
WED OCT.27, 1993 PAGE: 214
BYLINE: KIMBERLEY NOBLE
CLASS: ROB
DATELINE: WORDS: 504

**AECL SEEK ARBITRATOR'S HELP
Radioisotope pricing among disputes**

BY KIMBERLEY NOBLE
Health Industries Reporter

MDS Health Group Inc. and Atomic Energy of Canada Ltd. has asked an arbitrator - and could end up asking a judge - to help sort out a dispute over how much an MDS subsidiary must pay for products and services it buys from the federal atomic energy agency.

Toronto-based MDS said this week that its Nordian International Inc. subsidiary has entered into a prearranged arbitration process set out in a 1088 agreement between Nordion and AECL.

In addition, MDS has launched a separate legal action against AECL, Canada Development Investment Corp. and the federal government, the company said.

This lawsuit - which a MDS spokesman said is necessary because certain warranties built into the company's agreement to purchase Nordion from the federal government expire next month - asks the court to rule that AECL is required to complete construction of a long-delayed specially reactor, or else pay MDS $300-million in compensation.

The final dispute is about whether AECL has the right to ask Nordion to pay more for the radioisotopes it purchases from the Crown corporation.

The second is over whether the terms of the federal government's 1991 sale of Nordion - formerly AECL's sister company - mean that AECL is contractually bound to build its new Maple-X reactor, and whether it can ask Nordion to contribute more than the $20-million it has already invested in this project.

The Maple-X reactor has been in the development and licensing stages since the mid-1980s.

Nordion, 83 per cent owned by MDS, is described as a repackager and marketer of mildly radioactive materials used in medical diagnostic instruments, as well as a supplier of radiation-based systems used to sterilize medical equipment, waste products and food.

The federal government sold Nordion to MDS in 1991 for $165-million, with the CDIC acting as the broker.

MDS spokesman Ron Yamada said AECL's contractual obligations were among the assets that MDS purchased from the government. But last spring AECL claimed that regulatory and other factors, which led the agency to close one of its reactors in Chalk River, Ont., were unforeseeable events that would allow AECL to cancel and renegotiate the original agreement.

AECL also contends that it has no contractual obligations that would require it to finish building the Maple-X reactor, said William Hancox, AECL vice-president of technology and planning.

The first issue will be decided by an arbitrator some time next spring, Mr. Yamada said, after which MDS decide whether to proceed with the lawsuit. He said MDS is confident it can settle these issues without going to court.

In the meantime, AECL will continue to sell radioisotopes to Nordion under the terms of the 1988 contract. If an arbitrator rules in AECL's favour, it plans to charge higher prices retroactive to Sept. 27, 1993.

MDS Health Group shares, which last traded for $14.57, were halted yesterday on the Toronto Stock Exchange while the company fielded questions about the dispute.

FOCUS - 2 OF 26 STORIES

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The Financial Post

October 27, 1993, Wednesday, DAILY EDITION

SECTION: SECTION 1; News; Pg. 6

LENGTH: 261 words

HEADLINE: MDS TAKES ACTION ON AECL CONTRACT: Arbitration to settle dispute

BYLINE: SCOTT HAGGETT

BODY

A subsidiary of MDS Health Group Ltd.is trying to keep Atomic Energy of Canada Ltd. from walking away from a long-term contract.

Nordion International Ltd. is entering an arbitration proceeding with AECL to force it to continue supplying isotopes to Nordion.

AECL and Nordion are in the fifth year of a 23-year contract. Under the agreement, AECL is to supply radioactive isotopes made in its two Chalk River, Ont., reactors for Nordion's nuclear medical and industrial products business.

AECL shut down one of the reactors for repairs last March, but was unable to restart it. AECL claims this to be force majeure - a circumstance beyond its control that invalidates the contract.

"MDS doesn't believe this is an issue of force majeure," said MDS senior vice-president Ronald Yamada.

AECL spokesman Bill Hancox said the reactor was shut down because of safety and regulatory requirements. He declined to say if AECL would continue supplying Nordion with isotopes if his company wins the arbitration.

The three-person arbitration panel will consist of one each from Nordion and AECL and a third chosen by both.

MDS is also suing AECL and the Canada Investment Development Corp., the Crown agency from which MDS purchased Nordion in 1991 for $ 165 million.

MDS will be asking the Ontario Court general division to force AECL to complete a third reactor it has been building at the Chalk River facility. MDS said it paid $ 20 million toward the construction. Hancox confirmed Nordion had contributed funds, but declined further comment.

LANGUAGE: ENGLISH

LOAD-DATE-MDC: October 27, 1993

FOCUS - 1 OF 26 STORIES

Copyright 1993 Canada NewsWire Ltd.

Canada NewsWire

November 17, 1993, Wednesday

SECTION: Financial News

DISTRIBUTION: Attention Business Editors

LENGTH: 152 words

HEADLINE: **MDS HEALTH** GROUP LIMITED

DATELINE: TORONTO, Nov. 17

BODY

MDS Health Group Limited ("MDS") today announced that Nordion International Inc. ("Nordion") has, in the context of its ongoing dispute with Atomic Energy of Canada Limited ("AECL"), received a notice from AECL that AECL has initiated steps to discontinue further construction of a new Isotope reactor in Chalk River, Ontario.

As previously announced, **MDS and Nordion** will be seeking a ruling in court proceedings commenced against AECL, Canada Development Investment Corporation ("CDIC") and the Government of Canada that AECL has an obligation to complete the construction of the new reactor.

MDS and Nordion are pursuing the matter with AECL, CDIC and the Government and are also considering alternative legal and other initiatives. AECL is continuing to supply Isotopes to Nordion from an existing reactor at Chalk River, as required by the Supply Agreement between AECL and Nordion.

For further information: Douglas M. Phillips, Senior Vice-President Finance and Chief Financial Officer, (416) 213-4213; Ronald H. Yamada, Senior Vice-President New Technologies and Corporate Affairs; (416) 213-4224

LANGUAGE: ENGLISH

LOAD-DATE-MDC: November 17, 1993

EXHIBIT 3

United States Government — Department of Energy

memorandum

DATE: December 15, 1992

REPLY TO ATTN OF: NS-1

SUBJECT: Safety of the Omega West Reactor

TO: Richard Claytor
Assistant Secretary for Defense Programs

On December 11, 1992, an incident occurred at the Omega West Reactor at Los Alamos which raises questions about the adequacy of conduct of operations at the facility. The facility was directed by the Los Alamos Area Office to remain shut down until the area office has had the opportunity to formally address and review the incident. LAAO categorized the start-up as a Type 5.

Four months ago, on August 20, 1992, the Omega West Reactor experienced two instances in which eight control rods unexpectedly dropped without an alarm due to a degraded connector in the scram bus circuit. The connector was 36 years old. According to the contractor's occurrence report, an inspection program was not instituted when the reactor was built, and management currently does not have the resources to replace aging parts. The occurrence report goes on to note that "management must evaluate the most cost-effective way to maintain [the reactor's] aging systems," and that "where preventive maintenance is not practical, management must assess and prepare for the potential consequences of the eventual failure of aging parts."

I view both of these incidents as significant, and I am therefore requesting that the Omega West Reactor not be restarted until the Office of Nuclear Safety has had an opportunity to review conduct of operations, preventive maintenance, and the contractor's justification for continued operation of the facility prior to completion of a thorough study of potential aging effects.

Steven M. Blush
Steven M. Blush
Director
Office of Nuclear Safety

cc: V. Stello, DP-6
Jerry Bellows, LAAO
Bruce Twining, AL
Sig Hecker, LANL
Tom Rollow, NS-40
Don Brunell, NS-40/LANL

EXHIBIT Y

United States Government | Department of Energy

memorandum | Albuquerque Field Office

DATE: SEP 25 1992

REPLY TO ATTN OF: SPD

SUBJECT: Conclusions from Recent Nuclear Facility Appraisals at Los Alamos National Laboratory (LANL)

TO: S. S. Hecker, Director, LANL
THRU: J. L. Bellows, Area Manager, LAAO

Recently we conducted comprehensive multi-disciplined safety appraisals at two of our more significant nuclear facilities at LANL. I would like to share with you some of our conclusions and perceptions.

Appraisals at the Plutonium Facility (TA-55) and the Omega West Reactor resulted in concerns which are outlined in the attached summary sheets. The concerns were provided to LANL personnel during closeout briefings at each facility. It should be noted that the findings are, in general, original and not duplicative of previous Tiger Team findings.

With respect to the Plutonium Facility, we perceive there is a genuine commitment to upgrading the safety program to an exemplary level, and we hope that this commitment will continue. Progress, however, has been frustratingly slow. We recognize that new requirements and increasing demands by the Department of Energy and other federal and state institutions have taxed resources heavily. It may well be the case that part of the difficulty in implementing basic programs such as maintenance, pressure safety, and elevated work safety is resource related. Other possibilities may involve inappropriate priorities or inefficient utilization of LANL expertise.

Omega West Reactor has operated successfully without major incidents for more than three decades. We believe that this record is primarily a result of the highly competent staffing that has been maintained throughout the facility's history, including the current operating staff. However, there are indications that the risk profile is not as good as it should be. In the past few years, there have been a number of abnormal events at the reactor. For example: an incorrectly calibrated ion chamber allowed the reactor to reach 9.2 megawatts before an automatic scram shut down the reactor; an open beam port during reactor operations could have resulted in significant exposures had it not been detected during routine health physics monitoring; a radiation detector alarm above the reactor was not turned on while the reactor was operating; and a reactor start-up was initiated with some of the control rod latches not locked. While none of these incidents produced any significant consequences, they have not served to inspire us with confidence in the quality and discipline of operations. The most significant findings in the recent appraisal of Omega West Reactor involve the training program. We believe there is a relationship between the short-comings in the training program and these incidents, as well as other abnormal events. We perceive that there may be less than a strong commitment to a training program that meets current expectations. This will become even more important should the proposed Medical Isotopes Production Program be approved.

Most of the effort and new technology in plutonium processing during the coming years will occur at TA-55. It is essential that the safety programs be exemplary at this facility. The Medical Isotopes Production Program has been proposed for the Omega West Reactor and would involve major changes in reactor operations. New personnel, organizational support, equipment, and procedures will be required. The safety programs at the reactor site must accommodate these changes, as well as address the ongoing reactor operations in a diligent matter.

The personnel at LANL have a good attitude toward safety and are highly competent professionals. It is essential that we continue to develop and implement the programs necessary to manage the risks inherent in our operations and thereby achieve excellence in our safety programs.

Bruce G. Twining
Manager

2 Attachments

EXHIBIT 5

LA-UR-90-3287
Issued: September 1990

Reassessment of the Probable Lifetime of the Omega West Reactor

John L. Yarnell
Herbert T. Williams

Los Alamos
Los Alamos National Laboratory
Los Alamos, New Mexico 87545

drive motors, a digital data acquisition and control microprocessor, and a SUN-3 desktop workstation. The components and operation of the proposed system have been demonstrated on a development station. The system has been approved by the OWR Committee and the Laboratory's Reactor Safety Committee; it is now being considered by the DOE Albuquerque Operations Office.

3.5 External Systems

1) Underground Piping.

All of the underground coolant piping is made of 304 stainless steel. Corrosion and leaks should never be a problem. (Other reactors, which used aluminum piping underground, have had serious difficulties in this regard.)

2) Surge Tank.

The surge tank appears to have no structural problems. If the OWR cooling system were to become seriously contaminated (from, say, a failed fuel element) additional shielding and an improved vent filtration system might be needed. Installation of these additions would be straightforward.

3) Cooling Tower.

The cooling tower is a standard unit of commercial design, purchased in 1958 from a reputable vendor (Fluor Corporation). The structure is of treated redwood and is inspected biennially by qualified inspectors in accordance with Cooling Tower Institute (CTI) standards and procedures. Recommended repairs and reconditioning have been promptly accomplished.

In 1975 stainless steel heat exchangers were installed as replacements for the original aluminum units. New structural supports were installed, and the entire atmospheric section of the tower was rebuilt with new plastic pack and fill and drift eliminators of improved design. The lower spray-distribution system was also replaced. The use of stainless steel simplified the requirements for quality control of the water in the sump and significantly reduced the probability of primary coolant leakage due to corrosion in the heat exchangers.

The electrical power leads to the spray pump from the motor-control center were replaced in 1976.

In 1978, the existing fan, motor, stack, and gear box were replaced with units of improved design. In 1981 the outer asbestos cover of the tower was replaced with fiberglass to comply fully with environmental requirements.

In 1986, additional replacements of some of the major structural members in the tower were made. In 1988, the concrete basin for the secondary cooling water was replaced.

United States Government Department of Energy

memorandum

EXHIBIT 6

Ev [illegible] (w/NE -

– Bill

DATE September 15, 1993

REPLY TO ATTN OF DP-60

SUBJECT Omega West Reactor

TO Victor H. Reis, Assistant Secretary for Defense Programs
Everet Beckner, Principal Deputy Assistant Secretary
Thru: Victor Stello, Jr., Principal Deputy Assistant Secretary for Facilities

On September 13, 1993, a meeting was held with Mr. William White, Deputy Secretary of Energy, to discuss the future of the Omega West Reactor at the Los Alamos National Laboratory. Present at the meeting were Messrs. E.C. Brolin, J.D. Nulton, D.E. Erb, D. Dreyfus and myself. The memorandum prepared by the Office Nuclear Energy (NE), which proposed that NE go forward with repairs of Omega West Reactor and provide for operation of the reactor for radioisotope production, was the sole topic for discussion (Copy Attached).

The Office of Nuclear Energy indicated that it had discussed their proposal with other government agencies and industry medical companies and received encouragement to proceed; however, no source of external funding was identified. It was apparent that Deputy Secretary White would not move forward and require the controller to identify funds from within the Department of Energy to support the production of the medical isotopes. Deputy Secretary White made it clear that the Department should not unilaterally become the sole contributor to this program and if national health agencies and private industry were not willing to provide some capital, the Department would not become emersed in the Administrations' national health care problems.

As a representative of Defense Programs (DP), I indicated that DP planned to continue funding for Omega West only through the end of 1993 since the reactor is shutdown and there are no ongoing or planned DP projects for this facility. I also added that to the best of my knowledge, we in DP plan to declare the Omega West Reactor surplus and begin the transition of this facility from DP to EM.

Although NE will, in my view, continue to search for financial assistance outside the Department, it is highly unlikely that other agencies or industry groups will reverse their position. Therefore, I recommend to you that I be given permission to direct the Albuquerque Operations Office to advise Los Alamos National Laboratory to terminate plans for future operation, and commence closure and shutdown of the Omega West Reactor effective September 30, 1993. If approved, I will notify Mr. Brolin of your decision.

W L Beal
Donald F. Knuth
Deputy Assistant Secretary
for Facilities
Defense Programs

cc: E.C. Brolin
K. Ferlic

APPROVED ok - EB
DISAPPROVED ____________
DATE 9/16/93

DOE F 1325.8
(8-89)
EFG (07-90)

United States Government

EXHIBIT 7

Department of Energy

memorandum

DATE SEP 27 1993

REPLY TO ATTN OF DP-652 (R. Dintaman, 3-4142)

SUBJECT Omega West Reactor Permanent Safe Shutdown

TO Manager, Albuquerque Operations Office

Defense Programs (DP) has determined that it has no current or future programmatic need for the Omega West Reactor (OWR) at the Los Alamos National Laboratory (LANL). Therefore, you are authorized to direct LANL management to place the OWR in a permanent safe shutdown as soon as possible and to begin planning and preparing for facility transfer to the Office of Environmental Restoration and Waste Management (EM) for Decontamination and Decommissioning.

Mr. Terry Tracy, SNL/LANL Facility Management Division, Office of RD&T Facilities, is the DP action officer responsible for this activity. Your staff should work with him to complete the facility transfer to EM.

Weapons Research and Development is the source of funding to be used for these activities until the OWR facility is transferred to EM.

Donald F. Knuth

Donald F. Knuth
Deputy Assistant Secretary
for Facilities
Defense Programs

cc:
EM-1
NE-1
Manager, LAAO

EXHIBIT 8

Mike - FYI

Department of Energy
Washington, DC 20585

Octoher 14, 1993

Dr. J. F. Jackson
Deputy Director
Los Alamos National Laboratory
P.O. Box 1663
Los Alamos, New Mexico 87545

Dear Dr. Jackson:

Mr. William White, the Deputy Secretary, has asked me to respond to your September 20, 1993, letter regarding the Omega West Reactor (OWR). We are aware of the status of this reactor, including its possible use for producing medical radioisotopes within the Department of Energy Isotope Production and Distribution (IP&D) Program. We also recognize current issues, including a Defense Programs (DP) determination that there is no DP Program need for the OWR, and related direction to place the reactor in permanent safe shutdown. We are actively examining the matter of the OWR funding sources, repair and operation as part of an overall restructuring of the IP&D Program. We believe that actions which would increase the difficulty of restarting the Omega West Reactor should be avoided in the near term, when our consideration of the issues will be completed and decisions made. We will notify you of our conclusions promptly.

We appreciate your interest and support for the Isotope Production and Distribution Program.

Sincerely,

J. David Sutton
E. C. Brolin for
Acting Deputy Director
Office of Nuclear Energy

8/13/93 15:32 NE-46 → 5056654555

AUG-11-1993 08:47 FROM NECCC 202 586 6838 TO

202 586 6838

EXHIBIT 9

NO.784 P02

35434 P.01

Department of Energy
Washington, DC 20585

August 5, 1993

MEMORANDUM FOR THE DEPUTY SECRETARY

FROM: E. C. BROLIN, ACTING DIRECTOR, OFFICE OF NUCLEAR ENERGY

SUBJECT: ACTION: Restart of Omega West Reactor for Medical Isotope Production

ISSUE: The Department of Energy must decide whether to repair and restart the Omega West Reactor at the Los Alamos National Laboratory in New Mexico to produce molybdenum-99 (Mo-99), an essential medical isotope.

DISCUSSION:

- Nuclear medicine departments in hospitals all over the world use technetium-99, produced by the decay of Mo-99, for bone scan, brain scan, and other tracer tests. In the U.S. alone, more than 30,000 such tests are run each day (70 percent of all nuclear medicine procedures).
- Almost all of the Mo-99 and other short-lived medical isotopes used in the U.S. are produced by Canada in one government-owned reactor. Since Mo-99 has a half-life of less than three days, it cannot be stockpiled, and a shutdown of the production reactor for any reason will have an immediate impact on Mo-99 supply.
- It will be at least two years before a new Canadian reactor (Maple-X) will be running. Even if the new reactor operates, it is important that there be both a domestic source of Mo-99 and a backup to the Canadian reactor(s). A threat of a strike at the reactor last year caused major concern from the White House and Congress because of the potential disruption of medical care in the United States.
- The Office of Nuclear Energy has recently been approached by representatives from the nuclear medicine industry, including the Canadian supplier of Mo-99, regarding an urgent need for a backup production capability. The Annular Core Research Reactor at Sandia National Laboratory is one of several options being evaluated by the Canadians as a possible backup. Processing of Mo-99 and distribution to customers would be conducted in Canada. The Sandia reactor is not considered a viable option for long term domestic production of Mo-99 because of marginal capacity, high operating costs, and limited availability due to defense program commitments.
- Recognizing the risk of disruption in the supply of Mo-99, in 1990 the Department of Energy began an effort to develop a U.S. capability to produce these critical isotopes in the Omega West

Reactor, an eight megawatt research reactor operated by Defense Programs at Los Alamos. Production of Mo-99 in the Omega West Reactor was to begin by mid 1993; however, a high power scram incident and a coolant leak early this year caused the reactor to be temporarily shut down.

- It is recognized that the Maple-X reactor, when operational, will be in direct competition with Omega West. Although this may make the long-term operation of the Omega West Reactor unprofitable, the U.S. should not be dependent on a sole, foreign source for this essential medical isotope.

- Since 1990, Nuclear Energy has invested $8 million in the Omega West Reactor and related Mo-99 facilities. The decision to invest in Omega West assumed that the reactor would remain operational, that Defense Programs, as reactor landlord, would provide most of the reactor operating costs, and that revenue from Mo-99 production would offset remaining costs.

- The current situation is that:

  - The reactor remains shutdown and must be repaired before restart.

  - Defense Programs no longer has any programmatic mission for Omega West, and thus, does not need to repair the reactor or support operations.

  - The cost of repairs, upgrades, and restart of the reactor is estimated to be $0.5 million in FY 1993, $7.5 million in FY 1994, and $2.0 million in FY 1995. An additional $6.0 million in FY 1994 and $4.0 million in FY 1995 is required to subsidize Mo-99 production. Smaller subsidies might be required in out-years ($1-2 million/year).

- A Departmental initiative to ensure a reliable supply of this important medical isotope is considered to be worth the modest amount of funding required and is viewed as a contribution to a more viable health care system for the United States.

- The Office of Nuclear Energy's budget is extremely tight and does not have the means to support this initiative. The Controller has indicated that there is no readily available source of funds to support Omega West Reactor repair, and restart would have to be provided at the expense of other Department of Energy program(s). The Controller advises that because of the lateness in the year and the Hill's summer schedule, it will be very difficult to get a reprogramming through, even if an acceptable source of funds can be found.

ACTION:

- o Option 1 - Shutdown and decommission the reactor
  - No Mo-99 production source in the U.S.
  - Waste of $8 million spent to date to prepare for Mo-99 production
  - Least cost option
- o Option 2 - Complete modifications necessary to produce Mo-99; Nuclear Energy would dedicate the reactor to isotope production
  - Provides supply of essential medical isotope.
  - Provides tangible evidence of Administration desire to use Government to help the people.
  - Provides opportunity for the Department of Energy to visibly contribute to solution of the U.S. medical care problem.
  - Required funding is $0.5 million in FY 1993, $13.5 in FY 1994, and $6.0 in FY 1995.

  Out-year subsidies of about $1-2 million/year may also be required if isotope sales do not fully offset costs.

RECOMMENDATION:

- o Approve repair and restart of the Omega West Reactor, subject to safety reviews in accordance with Departmental Orders, for the production of isotopes, principally Mo-99 and related isotopes.
- o Transfer responsibility and financial obligations for repair and operation of the Omega West Reactor from Defense Programs to Nuclear Energy, effective immediately, with base funding for the Omega West Reactor for the remainder of FY 1993 to be provided by Defense Programs.
- o Request the Controller to identify options for providing $500,000 of FY 1993 funds and $13.5 million of FY 1994 funds to pay for repairs, upgrades, and restart of the reactor. (Defense Programs requests that this come from non-defense appropriations accounts.)

SECRETARIAL ACTION: Concur with the recommendation.

Approve: ______________

Disapprove: ______________

Date: ______________

CONCURRENCES: Defense Programs/Beckner/7-8-93
Congressional/Taylor/7-23-93
Public Affairs/Gauldin/7-22-93
Controller/Smedley/8-4-93

11/05/93 11:46 ☎202 586 7246 DOE Cong. Aff. 002

EXHIBIT 10

Halliburton NUS
CORPORATION

910 Clopper Road
Gaithersburg, MD 20878-1399
(301) 258-6000

May 25, 1993
GPAD-CS-93-0573

Mr. John Landis
4 Whispering Lane
Weston, MA 02193

Subject: Consultant Agreement
DOE Contract No. DE-AC01-90NE37980

Dear Mr. Landis:

Per your discussions with Mr. Richard Ireland, enclosed please find a consultant agreement for the subject contract.

Please provide the following to me by Friday, May 28, 1993.

1. A complete and signed Consulting Agreement (2 copies).
2. A signed statement that your proposed rate is a "Most Favored Customer Rate" (enclosed).
3. A signed Confidentiality Agreement.
4. A complete and signed Organizational Conflict of Interest Questionnaire and Statement (enclosed).
5. A complete and signed Representation and Certification Statement (enclosed).
6. A signed Procurement Integrity Certificate.
7. Three invoices to other clients supporting your hourly rate.
8. Resume.

This documentation will then be forwarded to the Department of Energy for approval under the subject contract.

Please submit your documentation by Federal Express to the following:

Halliburton NUS Corporation
910 Clopper Road
Gaithersburg, MD 20878-1399
Attn: Candy Sweitzer
Government Pricing

If you have any questions, please contact me at (301) 258-6035. Thank you for your assistance.

Sincerely,

Candy Sweitzer

Candy Sweitzer
Contract Specialist
Government Pricing and
Administration Department

IN WITNESS WHEREOF, the PARTIES hereto have caused this Agreement to be duly executed in their respective names.

Agreement Executed by:	Agreement Executed by:
Halliburton NUS Corporation	CONSULTANT
James W. Vaughan, Jr.	John Landis
Date:	Date:
	Social Security Number/Tax I.D.

Appendices

A. Statement of Work
B. Contract Clauses: Time and Material Contracts, DOE Supplement and Special Provision
C. Most Favored Customer Rate
D. Confidentiality Agreement
E. OCI Statement
F. Representations and Certifications
G. Certificate of Procurement Integrity

APPENDIX A
STATEMENT OF WORK

During the period June 1993 through May 1994, the CONSULTANT will provide approximately 400 hours of effort performing the following activities of support:

> Provide an independent assessment of the degree to which FFTF could be made self-supporting in light of Administration priorities by operating as a multi-mission facility, thereby offsetting investment and operating costs to the Department. Sources of revenue to be considered would be alternative government agencies and outside sources, e.g., international entities and the private sector. Included in this evaluation would be an assessment of the Department's decision to place the facility into cold shutdown. Provide a report to the Secretary and the delegation summarizing the conclusions of the review.

JOHN W. LANDIS
4 Whispering Lane
Weston, Massachusetts 02193

EXHIBIT 11

The Honorable Hazel R. O'Leary
Secretary of Energy
United States Department of Energy
Washington, DC 20585

September 20, 1993

Dear Madam Secretary:

It is my privilege to forward to you the enclosed report of the Independent Review Team on future use of the Fast Flux Test Facility (FFTF) at Hanford. The report is a composite of the views of all three of us on the Team and the findings and recommendations it contains represent a true consensus. These findings and recommendations are based on a comprehensive examination of all twelve missions that have been proposed for the FFTF.

Recognizing early in our study that production of radioisotopes and production of plutonium-238 are the key factors in determining the future viability of the FFTF, we devoted much effort and time to these potential missions. We compiled our own data bases and did the best we could in the short period of the study to verify critical information by interrogating knowledgeable individuals outside the FFTF staff. We encountered many different opinions, points of view, and interpretations of data as we made these contacts. We believe that we have drawn balanced and defensible conclusions from this input, however.

Our primary conclusion is that there is no combination of compatible missions for the FFTF that has a reasonable probability of making the facility financially viable in the foreseeable future (ten years). We have therefore recommended that the facility be shut down if you are satisfied that a crucial issue outside the scope of our assignment can be resolved. This issue is whether or not the department's remaining test reactors will have the capability to carry out the various missions they will be asked to perform, including the vital mission of supplying urgently needed medical radioisotopes, if the FFTF is permanently shut down.

There is widespread concern among users of medical radioisotopes that the nation's almost total dependence on foreign supply of these isotopes and the lack of a coordinated Federal Government plan for future domestic development and supply will result in a major crisis in the health-care industry at some point. Clarifying the roles of the department's test reactors may help to allay this concern.

We are disappointed that because of the limitations of our assignment we have been unable to resolve all the issues affecting future use of the FFTF. We are encouraged, however, by the dedication and competence of the many first-class scientists, engineers and administrators with whom we were privileged to work in this study and believe that under your leadership they will successfully meet the challenges posed by the test-reactor issue and the other open issues we have identified.

Because of the nature of our investigation, these relationships have been largely with the staff of the Westinghouse Hanford Company, but we have also greatly benefited from the advice and assistance of representatives of the City of Richland, the Office of the Governor of the State of Washington, and the Department of Energy, and from a generous contribution of time and effort by many individuals in various segments of the nuclear industry ranging from nuclear power generation to radioisotope production.

We shall thank all of these people in due course, but we want to say to you as we submit our report that in them we believe you have a tremendously valuable national resource. We know from the announcements that you have already made that you fully intend to find productive assignments for them, and in this endeavor we wish you much success.

If you have any questions regarding our report, please have your staff call any or all of us and we shall be happy to respond.

Sincerely,

JWLandis

John W. Landis
For the Independent Review Team:
F. P. Baranowski
E. H. Klevans
J. W. Landis

JWL:bg

Enclosure

EXHIBIT 12

Long-Range Plan for the Utilization,
Retirement, and Replacement
# of Department of Energy Nondefense
Test and Research Reactors

Approved:

Martha Krebs

Martha A. Krebs
Director
Office of Energy Research

11/22/93
Date

Daniel A. Dreyfus
Acting Director
Office of Nuclear Energy

11/12/93
Date

Long-Range Plan for the Utilization, Retirement, and Replacement of Department of Energy (DOE) Nondefense Test and Research Reactors

I. Introduction

This plan is responsive to two reports: U.S. General Accounting Office (GAO) report of July 15, 1992, entitled "Nuclear Science: Monitoring Improved, But More Planning Needed for DOE Test and Research Reactors" and the report of an independent review team, issued September 20, 1993, entitled "Future Use of the United States Department of Energy's Fast Flux Test Facility."

The GAO report contained one recommendation as follows:

> "To avoid possible degradation in safe operation, increased operating costs, degradation in performance, and gaps in needed reactor service, we recommend that the Secretary of Energy require that the manager of DOE's test and research reactor facilities develop a long-range plan for the timely retirement or replacement of aging reactors. In their analysis of the possible need to eventually replace the Department's two older operating category "A" test reactors, DOE planners should consider the cost and benefits of using the Fast Flux Test Facility, now on standby, as a possible replacement rather than constructing a newer, more expensive reactor."

The DOE provided comments on the GAO report. DOE stated that it had no need to replace the existing Category A test and research reactors at this time, and the Fast Flux Test Facility (FFTF) would not be a suitable replacement for the Experimental Breeder Reactor-II (EBR-II) or the Advanced Test Reactor (ATR). The Department also committed to complete a long-range plan for the retirement or replacement of test and research reactors by September 30, 1993.

The independent review team's report included a finding that reads:

> "The Department of Energy does not have a comprehensive policy for utilization of its test reactors and therefore the need for the FFTF to meet high-priority requirements is unclear."

This document provides the Department's long-range plan for the utilization, retirement, and replacement, as required, of the DOE nondefense test and research reactors.

DOE reactors are classed into two categories: Category A and Category B. The Department's Category A reactors are operated at a power level at or above 20 megawatts thermal, whereas DOE Category B reactors are operated at power levels below 20 megawatts.

DOE currently has four Category A nondefense reactors in operation, one in hot standby and one in the design phase. Operating reactors include the High Flux Beam Reactor (HFBR) at the Brookhaven National Laboratory (BNL), the High Flux Isotope Reactor (HFIR) at the Oak Ridge National Laboratory (ORNL); the EBR-II at the Argonne National Laboratory-West (ANL-W), and the ATR at the Idaho National Engineering Laboratory (INEL). The FFTF located at the Hanford

Reservation near Richland, Washington, is in hot standby. The Advanced Neutron Source (ANS) is in the design stage.

Operating Category B nondefense reactors include the Brookhaven Medical Research Reactor (BMRR) at BNL, the Neutron Radiography Reactor Facility (NRAD) and the Transient Reactor Test Facility (TREAT) at ANL-W, and the Advanced Test Reactor Critical Facility (ATRCF) at INEL. The Zero Power Physics Reactor (ZPPR) at ANL-W is in standby. A listing of operational, standby, and shutdown Category B reactors is provided in Table 1.

The reference plan set forth in this document is based on the current and planned utilization of each of the reactors, the planned duration of the missions for the various reactors, and the projected operating life of the reactors. The plan identifies the available capabilities of the operating reactors to satisfy additional DOE mission requirements. Uncertainties that can affect the ultimate implementation of the plan include: 1) DOE mission changes that eliminate the need for continued reactor operation or establish new requirements that result in expanded utilization of existing reactors or replacement of a reactor not currently planned to be replaced, 2) unanticipated degradation in the safety of a facility, 3) reductions in the availability of a reactor adversely affecting cost effectiveness of continued safe operation, 4) failure to receive sufficient appropriations for continued safe operation, and 5) delay in the construction and start of operation of the ANS. Should any of these conditions occur, this plan will be reevaluated and adjusted accordingly.

2. DOE Nondefense Requirements

Current and projected DOE program requirements for nondefense reactors can be categorized into seven areas. These areas include material irradiations, fuel testing, safety testing, neutron scattering, activation analysis, medical research, and isotope production. The following provides a brief description of each of these requirements.

Materials Irradiation: Materials exposed to irradiation undergo changes that affect their structural properties. Therefore, it is essential that materials that are planned for use in a neutron environment be tested. This research provides data that is vital to ensuring the safety and reliability of materials selected for use in fission and fusion applications.

Fuels Testing: Specific fuel element designs are subjected to conditions of normal operation, expected operational transients, various levels of burnup, severe conditions of transient overpower, and loss of cooling. This testing is conducted to determine fuel behavior and to predict margins of safety with specific fuel element designs and to validate the various analytical tools used in final design. This research is vital in providing data for design of efficient reactor cores that meet safety and reliability goals.

Safety Testing: Testing is performed to characterize safe inherent responses to reactor off-normal and accident conditions. This testing provides plant dynamic response for design and development of inherent reactor control systems as well as establishing the margins of safety in various reactor fuel systems.

Neutron Scattering: Neutrons of various energy levels are used to analyze the relationship between molecular structure and physical properties of materials, such as a high temperature superconductors, magnetic materials, metal alloys, polymer gels, and biological materials. These tests are conducted external to the reactor core utilizing beam tubes.

Activation Analysis: Following the exposure of sample materials to radiation and their activation, gamma ray spectroscopic analysis of the decaying isotopes identifies elemental composition of the sample in order to detect impurities or contaminants.

Medical Research: The utilization of neutron beams to evaluate and develop treatments for tumors in humans.

Isotope Production: Isotope targets are placed in the reactor's high neutron flux to produce radioactive sources used in research, industrial radiography, and medical testing and therapy procedures.

As is shown below, the operating reactors fully meet the irradiation requirements of the Department's civilian and Naval Reactors programs.

Table 1

PROGRAM REQUIREMENTS FOR DEPARTMENT OF ENERGY NONDEFENSE TEST REACTORS

PROGRAM	REQUIREMENT	REACTORS					
		ATR	EBR-II	HFIR	HFBR	TREAT	BMRR
Actinide Recycle	Materials Irradiation		X				
	Fuels Testing		X				
	Safety Testing		X			X	
Naval Reactors	Materials Irradiation	X					
	Fuels Testing	X					
Energy Research	Materials Testing		X	X	X		
	Fuels Testing			X			
	Neutron Scattering			X	X		
	Neutron Activation Analysis			X	X		
	Medical Research						X
	Isotope Production			X	X		X
Isotope Production and Distribution	Isotope Production	X		X			

3. Summary

This section provides a summary of the plan for the utilization, retirement, and replacement, as required, of the Department's nondefense reactors. Details are provided in Section 4.

The ANS, currently in the advanced conceptual design phase, is the planned replacement reactor for the HFIR and the HFBR to conduct programs in support of the missions of the Office of Energy Research. The Department's FY 1994 budget submission proposed that the ANS be authorized as a line item project leading to start of operation in FY 2002. However, consistent with the Office of Management and Budget's (OMB) October 13, 1993, letter to Senator J. Bennett Johnston, Jr., Congress did not appropriate funds for ANS as a line item and instead provided funding only for conceptual design, research and development, safety, regulatory, and compliance tasks. FY 1994 activities will include the conduct of a study to quantify the performance levels obtainable with various fuel enrichment levels. This study is planned for completion in February 1994. Appropriate updates to the plans and schedule for the ANS will then be made.

Current plans are to continue HFBR and HFIR operations until the ANS is placed in operation. A material surveillance program required by the Technical Specifications at both HFBR and HFIR provides the technical basis to ensure that these reactors are in a condition for continued safe operation.

The EBR-II mission, which is to support the demonstration of the Nuclear Energy Actinide Recycle Program, is planned to be completed in FY 1996, well within the projected life of the facility. The reactor will be placed in an industrially and radiologically safe shutdown condition by the end of FY 1998. There are no plans to replace the EBR-II.

The ATR, which is operated principally in support of the Naval Reactors Program, is projected to be operational until at least 2014. No replacement reactor is currently planned.

The FFTF was placed into hot standby condition in April 1992. No missions have been identified that justify the cost of its operation. A decision is pending regarding the future of this facility.

No replacement reactors are planned for the Category B nondefense test and research reactors. Reactors that are shutdown are not planned for restart. Plans are to continue the operation of the BMRR in support of the Office of Energy Research program mission to demonstrate the successful treatment of cancer in humans using boron neutron capture therapy. As a result of the restructured Advanced Liquid Metal Reactor (ALMR) programs, the TREAT will be placed in standby and the ZPPR and NRAD facilities will be shut down beginning in FY 1994. The TREAT reactor will either be operated or shut down depending on the results of ongoing discussions with the Japanese for participation in the restructured ALMR program. The ATRCF will continue to operate as long as needed in support of ATR operation.

As described above, and in more detail in Section 4, the planned utilization and shutdown of the nondefense test and research reactors are consistent with all identified needs within the Department. The operating reactors not only meet identified mission needs but have unused capabilities and capacity to satisfy additional DOE mission requirements.

4. Specific Reactor Missions and Lifetime Information

4.1 ANS

The ANS, currently in the advanced conceptual design phase, is planned as a heavy-water cooled and moderated reactor using highly enriched uranium silicide fuel clad in aluminum and positioned in a replaceable core pressure boundary tube. Surrounding the core pressure boundary tube will be an unpressurized tank of heavy water that serves as a neutron reflector and moderator. Materials irradiation and transplutonium production targets will be located inside the core pressure boundary tube near the core while beam tubes and other irradiation facilities are located in the reflector tank. The reflector tank will also contain two "cold sources" that serve as the source of cold and very cold neutrons for experimentation. There are four major buildings planned: the reactor containment building, the reactor support building, the guide hall building, and the office building. The design operating lifetime is 40 years. Final site selection has not yet been made, but ORNL has been identified as the preferred site.

The mission of the ANS is to support research programs for the Office of Basic Energy Sciences in the Office of Energy Research. The ANS is intended to replace both the HFBR and the HFIR with a state-of-the-art research facility that would serve as the cornerstone for advanced neutron research well into the next century. The ANS will increase the neutron research capability in the United States by producing high flux neutrons for experiments in physics, chemistry, materials science, and biology; by enabling research related to materials irradiation and activation analysis; and by producing isotopes necessary for industrial applications, medical research, and for certain forms of cancer therapy.

The ANS will enable the United States to regain the lead, lost to Europe approximately ten years ago, in neutron scattering research, one of the most important cross-disciplinary research areas of fundamental and applied science and materials engineering for advanced manufacturing technologies. Industrial groups will also regain much needed research and production capabilities within the Nation's borders. The ANS would accommodate approximately 1,000 users per year from industry, universities, and Federal laboratories and has the potential to attract many new students into the sciences by offering them the chance to engage in many widespread areas of research.

The ANS plan had been based on starting operation in FY 2002, assuming that ANS would be authorized as an FY 1994 line item project. Subsequently, OMB, in an October 13, 1993, letter to

Senator J. Bennett Johnston, Jr., advised that the Department will require only $12 million for research and development and that the Department has decided to defer construction in order to study the impact on ANS performance goals if the design is changed to use low or medium enriched fuels. The conferees report provided $17 million for ANS activities in FY 1994, $5 million more than requested in OMB's letter to Senator Johnston. In FY 1994, the Department will conduct those activities called for in the conferees report that include continuation of advanced conceptual design, research and development, reactor safety and regulatory compliance tasks, and continued work on the draft Environmental Impact Statement. FY 1994 activities will include the conduct of a study to quantify the performance levels obtainable from various fuel enrichment levels. The study is planned for completion in February 1994. Appropriate updates to the plans and schedule for the ANS will then be made.

4.2 HFBR

The HFBR, located at BNL, began operation in 1965 and operates at a power level of 30 MW. The HFBR uses U-235 fuel and a heavy water moderator. The core consists of 28 elements, each containing 19 curved fuel plates. Each plate has a core of uranium oxide with an aluminum cladding. The fuel elements are placed in a roughly cylindrical arrangement inside a spherical-shaped aluminum reactor vessel. The core is approximately 19 inches high and 21 inches in diameter, has an active volume of about 97 liters, and contains a maximum of 9.83 kilograms of U-235. The heavy water moderator is pumped downward through the spaces between the fuel element plates at a pressure of approximately 200 psig. The heavy water is circulated through a pair of heat exchangers where the heat is transferred to a light water secondary loop that dissipates the heat into the air through a set of cooling towers.

In contrast to most reactors, which are designed to minimize the escape of neutrons from the core, the HFBR has been expressly designed to maximize the number of neutrons available in external beams. The volume of heavy water flowing through the core to cool the fuel elements does not provide sufficient moderation to thermalize all the neutrons within the core. This results in a unique neutron distribution in which the useful thermal neutron population peaks in the reflector where the neutrons are directly accessible to the beam tubes.

The mission of the HFBR is to support research programs for the Office of Basic Energy Sciences in the Office of Energy Research. The reactor supplies intense beams of thermal neutrons for neutron scattering experiments in a wide variety of basic research applications in physics, chemistry, materials science, and biology. In addition, the reactor provides irradiation facilities for neutron activation analysis, radiation damage studies, and isotope production for experimental and medical purposes. Currently, about 15 percent of the capacity for irradiation for neutron activation analysis is available to satisfy additional requirements.

The missions being fulfilled by the HFBR are expected to continue well into the next century. Current planning calls for the HFBR to be shut down after the ANS is placed in operation. A material surveillance program required by the Technical Specifications provides the technical basis to ensure that the HFBR is in a safe condition for continued operation. The BNL white paper entitled "Aging and Life Extension of the HFBR Reactor Vessel," dated February 1991, justified the safe operation of the reactor vessel beyond the 25-year design lifetime that was reached in October 1990. This conclusion is based on extensive materials analysis and testing that was performed in response to recommendations by a committee chaired by Dr. Paul Shewmon and the continuing materials surveillance program required by the Technical Specifications. As required by the Technical Specifications, a material specimen will be removed from the HFBR reactor vessel and examined in 1996. If the examination demonstrates adequate beam tube ductility, operation would be allowed until 2001 when another material surveillance will be performed.

4.3 HFIR

The HFIR, located at ORNL, began operation in 1966 and operates at a power level of 85 MW. The reactor core consists of two concentric cylindrical fuel elements. The inner element is approximately 31 inches high and 5 inches thick, with 171 individual fuel plates. The outer element is approximately 31 inches high and 6 inches thick, with 369 individual fuel plates. These fuel plates are highly enriched uranium oxide with an aluminum cladding. The HFIR primary system operates at a pressure of approximately 468 psig and a temperature of 120 degrees Fahrenheit. This primary coolant is circulated through heat exchangers that are cooled by a set of cooling towers adjacent to the HFIR building.

HFIR is a flux-trap reactor designed to provide an intense flux of neutrons on the order of 10^{15} neutrons/cm^2/sec. This intense flux is needed to produce transuranic radioisotopes efficiently.

The mission of the HFIR is to support research programs for the Office of Basic Energy Sciences in the Office of Energy Research. The reactor supplies neutrons for neutron scattering experiments in a wide variety of basic research applications in physics, chemistry, and biology. In addition, the reactor provides irradiation facilities for testing fuels and materials. The reactor is also used for the production of californium-252, iridium-192, and other isotopes for research, industrial, and medical applications. Currently, about 25 percent of the capacity for isotope production and material irradiation is available to satisfy additional requirements. The HFIR, as well as the ATR, can be utilized to conduct irradiation testing required for the fusion program. Use of these two reactors, in coordination with possible use of foreign fission reactors, will provide the testing required to support the future demonstration fusion reactor that is planned under the International Thermonuclear Experimental Research program.

The missions being fulfilled by the HFIR are expected to continue well into the next century. Current planning calls for the HFIR to be shut down after the ANS is placed in operation. A vessel surveillance program required by the Technical Specifications provides the technical basis to ensure that the HFIR is in a safe condition for continued operation. This Technical Specification requirement is based on the ORNL study, "Evaluation of HFIR Pressure Vessel Integrity Considering Radiation Embrittlement," dated September 1987. The results of the 1992 hydrostatic test of the HFIR vessel demonstrated that the HFIR can continue to be used for at least an additional 10 effective full-power years of reactor operation before another test would be required by the ASME Section XI code. Annual hydrostatic tests are performed at HFIR to ensure vessel integrity.

4.4 ATR

The ATR, located at INEL, began operation in 1969. The ATR is a 250 MW water-cooled reactor designed to study the effects of intense radiation on samples of reactor materials, including fuels. The core fuel is 93 percent enriched U-235 with aluminum cladding. The ATR is a low temperature (240 degrees Fahrenheit), low pressure (390 psi) reactor. The reactor vessel is fabricated of solid stainless steel and is 12 feet in diameter by 35 feet high. There are 16 control cylinders, 2 regulating rods, and 6 safety rods in the core. There are 40 fuel assemblies with 19 fuel plates in each assembly. U-235 content of each assembly is 1075 grams. There are more than 100 irradiation ports for materials irradiation and isotope production. The ATR has nine independent pressurized loops in its core. The loops have a pressure range of 300 to 3400 psi, and a temperature range of 200 to 600 degrees Fahrenheit. The high power density and the ability to adjust the flux to meet specific loop experimental requirements result in intensive irradiation that saves considerable testing time. The effects of years of radiation can be duplicated in months or weeks in the ATR.

The mission of the ATR is to support research programs for the Office of Naval Reactors in the Office of Nuclear Energy. The ATR produces a neutron flux that simulates long-duration radiation effects on materials and fuels used in the U.S. Navy nuclear power program. This research has been and continues to be vital for ensuring safe and reliable operation of Navy nuclear propulsion plants. The ATR is also used for production of isotopes used in medicine, research, and industry.

With the end of the Cold War, Naval Reactors has scaled back the pace of its testing program, thus making reactor usage available for other sponsors. Only five of the nine loops are planned to be utilized by Naval Reactors beginning in early 1994.

The ATR has additional capabilities that DOE can take advantage of in meeting potential future needs, including 1) conduct of irradiation experiments for other DOE programs, 2) production of additional isotopes for research, medical, and industrial purposes, and 3) production of Pu-238 if a decision is made to pursue a domestic option to supply this isotope for space and defense missions.

As previously discussed, the ATR, as well as the HFIR, can be utilized to conduct irradiation testing required for the fusion program.

Currently, the facility produces iridium-192, cobalt-60, and nickel-63. The production rate could far exceed the current demand. With appropriate facility modifications, numerous other isotopes, including molybdenum-99, an important medical isotope, could be produced in the ATR.

The current U.S. inventory of Pu-238, augmented by a planned purchase of 40 kgs from Russia over the next several years, should be sufficient to meet the currently planned missions through the late 1990s. However, additional material will be needed for projected missions beyond the turn of the century. Potential foreign sources to meet these projected missions included additional purchases from Russia or purchases from either France or England.

If a decision is made to maintain a domestic supply, the ATR could be used to produce up to 13 kgs of Pu-238 per year. A lead time of around eight years and an investment of $300 million for processing facilities would be required; but even with this investment, the unit cost of the material should be competitive with other U.S. facility options.

No date has been identified for completing the ATR mission at this time. The current lifetime goal is for operation through at least 2014 that would achieve 45 years of power operation. The ongoing ATR Aging Management Program, established in 1986, has identified no safety or availability reasons why this goal cannot be accomplished. At the present time, no replacement facility is planned.

4.5 EBR-II

The EBR-II, located at ANL-W, began operation in 1964. The EBR-II is a liquid metal pool-type reactor plant with a thermal power rating of 62.5 MW. It consists of an unmoderated, heterogeneous, sodium cooled reactor, an intermediate closed loop of secondary sodium coolant, and a steam plant that produces 19 MW of electrical power through a conventional turbine generator. The reactor core, reflector, blanket, neutron shield, primary pumps, primary piping, heat exchanger, and in-vessel handling equipment are completely submersed in sodium. The reactor core has 637 positions for hexagonally shaped subassemblies; 127 of these positions may be used for driver subassemblies containing 61 fuel pins or for irradiation test vehicles. The remaining positions are occupied by stainless steel reflector or depleted uranium blanket subassemblies. The reference driver fuel is 90 parts uranium, 10 parts zirconium alloy, with the uranium being 67 percent enriched in U-235.

The mission of the EBR-II is to support research programs for the Office of Civilian Reactor Development in the Office of Nuclear Energy. The EBR-II has been a key facility in the ALMR/Integral Fast Reactor development program. With the redirection of the Advanced Reactor research and development program to focus on the Actinide Recycle Program, the current plan is to initiate shutdown activities at the EBR-II beginning in October 1993. Shutdown activities to be conducted in the FY 1994 to 1996 timeframe will be removal of the blanket subassemblies, replacement with stainless steel dummy subassemblies, and processing of the blanket subassemblies in the Fuel Cycle Facility, also located at ANL-W, to place the material into a form suitable for acceptance into a future high-level waste repository. The reactor will operate through FY 1996, in parallel with the shutdown activities, to support the demonstration of actinide recycle technology.

The current identified date for completing the EBR-II mission is the end of FY 1996. An ANL life extension study, "Technical Basis for Operation of EBR-II to a 40-year Life," dated May 1992, did not identify any life-limiting EBR-II reactor component for a 40-year lifetime. Thus, the plant could be operated until at least 2004. Its mission will be fulfilled within this time period. A replacement facility for the EBR-II is not planned.

4.6 FFTF

The FFTF, located at the Hanford Reservation near Richland, Washington, began operation in 1982. The FFTF is a loop-type sodium cooled, low pressure, fast spectrum nuclear reactor constructed for the irradiation testing of reactor fuels and materials and for the long-term testing of plant components and systems. It has a power rating of 400 MW. There are three primary heat transport systems that remove heat from the core and deliver it via three intermediate heat exchangers and three secondary heat transport systems to large air-cooled heat exchangers for final dissipation. The reactor provides extensive capability for in-core irradiation testing, including eight core positions that may be used for independent instrumentation. The reference fuel system is mixed uranium-plutonium oxide; pins containing the fuel pellets are loaded in hexagonal ducts to form the fuel assemblies.

The FFTF has provided support for civilian nuclear energy, space and defense power, fusion energy, and other programs as a broad-based national irradiation facility for fuels and materials development. In April 1992, DOE placed this facility in hot standby pending the results of additional efforts to identify a significant long-term mission that would justify its continued operation.

In early 1993, the Department advised Congress that the reactor would be placed in cold standby beginning in February 1993. However, subsequent deliberations between Congress and the Secretary of Energy resulted in a decision to defer cold standby pending the conduct of an independent study to explore a multimission role for this facility. A report on the independent study was submitted to the Department on September 22, 1993.

The report provides the results of the independent evaluation of 12 potential missions that could be performed in the FFTF but concludes that there is no combination of compatible missions that has a reasonable probability of making FFTF financially viable in the foreseeable future (ten years). The independent review team recommends that FFTF be shut down if the remaining DOE test reactors are adequate to meet all current and planned mission requirements. Most of the missions addressed by the team are not essential. Those missions included in the review that are essential to the Department's role are either currently being fulfilled or can be fulfilled by other reactors within the Department. The Department is currently reviewing the report, following which a decision on the future of FFTF will be made.

The GAO report suggested that the FFTF be considered as a possible replacement for the EBR-II and ATR. The DOE response to the GAO report provided a discussion of why this would not be feasible. The discussion remains valid today.

The use of the FFTF as a possible alternative to the construction of the ANS was considered. The FFTF cannot fulfill the mission of the HFBR, HFIR, or planned ANS. It does not have the thermal fluxes nor the beam tubes essential for the conduct of neutron scattering experiments.

4.7 Category B Reactors

A listing of Category B nondefense test and research reactors is provided in Table 1. Those reactors, which are identified as being shutdown, are not planned for restart, and no replacement reactors are planned. Plans for the five reactors that are currently operational or in standby are discussed herein.

The BMRR at BNL is operated to support research programs for the Office of Health and Environmental Research in the Office of Energy Research. The reactor provides large area filtered neutron beams for experimental research and boron neutron capture therapy. In addition, the reactor provides irradiation facilities for neutron activation analysis and the generation of isotopes for experimental purposes. Radiation damage due to exposure of material to neutrons is negligible because of the relatively low neutron fluence in this reactor. The preventative maintenance program and safety system surveillance testing program ensure that replaceable components remain functional or are replaced when necessary. Plans are to continue the operation of the BMRR to achieve the successful demonstration of treating cancer in humans. Once the mission has been completed, the facility will be shut down. There are no plans to replace the BMRR at this time.

NRAD, TREAT, and ZPPR are three Category B reactors at ANL-W that in recent years have been utilized to develop the technology required to demonstrate the technical feasibility, safety, and economics of the ALMR. With the redirection of the current program to focus on actinide recycle, the NRAD and ZPPR are are no longer required and consequently will be shut down beginning in FY 1994 and placed in an industrially and radiologically safe condition. The TREAT will continue to be operated if ongoing discussions with the Japanese result in their financial participation in the restructured program; otherwise, TREAT will be shut down in FY 1994.

The ATRCF at INEL is a very low-power Category B reactor whose core region is nearly identical to the ATR. The ATRCF is housed in the

ATR building in an extended portion of the ATR canal. The ATRCF is used to obtain accurate and timely data on nuclear characteristics of the ATR core in order to ensure safe, efficient, and reliable operation of the ATR. Data obtained includes rod worth, modeling data for estimated critical position calculations, excess reactivities, neutron flux distributions, gamma heat generation rates, fuel loading requirements, and effects on reactivity of the insertion and removal of planned experiments. The ATRCF is planned to operate as long as needed in support of ATR operations. A replacement is not planned.

EXHIBIT 13

Department of Energy
Washington, DC 20585

OCT 23 1992

The Honorable Mike Synar
Chairman
Subcommittee on Environment, Energy, and
Natural Resources
Committee on Government Operations
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

The General Accounting Office (GAO) issued its report RCED-92-123 entitled "Nuclear Science: Monitoring Improved, but More Planning Needed for DOE Test and Research Reactors" containing a recommendation for the Department of Energy (DOE). DOE has provided comments on the report to the House Committee on Government Operations, the Senate Committee on Governmental Affairs, and the House and Senate Committees on Appropriations. Because of your Subcommittee's interest in the subject matter, a copy of the DOE response is enclosed for your information.

DOE would be pleased to provide any additional information that is desired in this matter.

Sincerely,

Elizabeth E. Smedley
Elizabeth E. Smedley
Acting Chief Financial Officer

Enclosure

DOE COMMENTS ON GAO REPORT
"NUCLEAR SCIENCE: MONITORING IMPROVED, BUT MORE PLANNING NEEDED FOR DOE TEST AND RESEARCH REACTORS"
GAO/RCED-92-123

The following are the General Accounting Office (GAO) recommendation and the Department of Energy (DOE) related comments.

GAO Recommendation

"To avoid possible degradation in safe operation, increased operating costs, degradation in performance, and gaps in needed reactor service, we recommend that the Secretary of Energy require that the manager of DOE's test and research reactor facilities develop a long-range plan for the timely retirement or replacement of aging reactors. In their analysis of the possible need to eventually replace the Department's two older operating category "A" test reactors, DOE planners should consider the cost and benefits of using the Fast Flux Test Facility, now on standby, as a possible replacement rather than constructing a newer, more expensive reactor."

DOE Comments

The Department will develop a long-range plan for the utilization of the nondefense test and research reactors by September 30, 1993.

With the exception of the High Flux Beam Reactor, which has an estimated remaining lifetime of 8 to 25 years, all of the Category A test and research reactors have a remaining lifetime of over 10 years. Also, the appropriate material surveillance programs are in place to continue to monitor aging conditions. Thus, the September 30, 1993, completion date will not adversely affect the continued safe and reliable operation of these facilities.

The GAO report suggested that the Fast Flux Test Facility (FFTF) be considered as a possible replacement for the Experimental Breeder Reactor II (EBR-II) and the Advanced Test Reactor (ATR).

There is currently no need identified for a replacement of EBR-II. EBR-II has more than adequate lifetime to complete the Integral Fast Reactor (IFR) program. The IFR program is a modular version of an advanced liquid metal cooled reactor concept using metal fuel under development at Argonne National Laboratory-West (ANL-W). In 1986, the Department selected ANL-W as the site to continue IFR technology development because: (1) EBR-II was available with metal fuel already under irradiation; (2) support facilities existed at ANL-W to manufacture and examine the metal fuel; (3) operating costs at FFTF were about $50 million per year more than at EBR-II; (4) approximately 3 years of schedule would be lost in transferring the IFR program from ANL-W to Westinghouse Hanford. The above reasons for using EBR-II for the IFR program are still valid today.

There are also no life-limiting conditions that would preclude operation of ATR well into the next century. Since FFTF produces a fast neutron flux spectrum, a major redesign of FFTF and the experiments would be required to supply the thermal and epithermal flux spectrums provided at ATR. Additionally, FFTF does not have the required power density, experiment space, and poses material compatibility concerns for the type of experiments performed at ATR.

In summary, the Department will complete a long-range plan for the retirement or replacement of the test and research reactors by September 30, 1993. We have no need to replace the existing Category A test reactors at this time and FFTF would not be a suitable replacement for either of the reactors.

EXHIBIT 14

include at least one large guide hall for cold neutron and thermal neutron research; a reactor hall for thermal neutron and high-energy (hot source) neutron research; a variety of advanced research instruments; and improved national facilities for isotope production, irradiation of materials, neutron activation analysis, and research in nuclear physics. The top-level research goals of the ANS Project are listed in Table 1.2-1.

Table 1.2-1. ANS Project research goals

To design and construct the world's highest-flux research reactor for neutron scattering

- Provide 5-to-10 times the flux of the best existing facilities

To provide isotope production facilities that are as good as, or better than, the HFIR

To provide materials irradiation facilities that are as good as, or better than, the HFIR

1.3 PROJECT SCOPE

The ANS Project includes all aspects of the design and construction of ANS defined in the Field Budget Request project data sheet 94-ORNL-KC(AF)-1[16] dated April 2, 1992. The project also includes (1) safety analyses and documentation to support funding requests and permitting; (2) environmental reports, assessments, and impact statements to support funding requests and permitting; and (3) research and development necessary to provide data for the safety analyses, environmental analyses, and design. All work elements within the project are defined by a work breakdown structure (WBS) (Fig. 1.3-1).

The scope of the project has been defined through comprehensive interaction with all of the relevant scientific communities whose purposes may be served by ANS. Contacts have been fostered by widespread discussion and dissemination of information about the project at national and international professional society meetings, by journal articles, by seminars, by both broad-based and focused newsletters, by mailed questionnaires, and by direct personal contacts within the neutron research community. The NSCANS has served as a clearinghouse for the information garnered and has acted as a review body, both directly and via special subcommittees.

The project will construct a neutron research laboratory based on a high-flux reactor. The reactor will also provide materials irradiation and transuranic isotope production capabilities that match or exceed the capabilities of the High Flux Isotope Reactor (HFIR). Facilities for radioisotope production and for analytical chemistry will be accommodated in the reflector. Safe operation of the reactor and efficient utilization of the experimental facilities will be provided by a suitable on-site infrastructure, appropriately interfaced with the facilities offered locally by the Oak Ridge Reservation (ORR) and by other DOE operations.

EXHIBIT. 15

Table 1.2 ANS conceptual design parameters

Parameter[a,b]	NSCANS goals	ANS conceptual design
Neutron scattering		
Hot neutrons		
Thermal flux at hot source	≥1	1
Number of hot sources	1	1
Number of hot beams	2	2
Thermal neutrons		
Thermal flux in reflector	5–10	7[c]
Thermal:fast ratio	≥80:1	170:1
Number of thermal tangential tubes	7	7
Cold neutrons		
Thermal flux at cold sources	2–4	4
Number of cold sources	2	2
Number of horizontal cold guides	14	14
Number of slant cold beams for scattering instruments	1	1
Nuclear and fundamental physics		
Number of thermal through tubes	1	1
Number of slant thermal beams	1	1
Number of very cold beams	2	2
Materials irradiation[d]		
Central irradiation facility		
Fast flux	≥1.4	2.0[c]
Fast:thermal ratio	≥1:2	2.9:1[c]
Total number of positions	10	10
Number of instrumented positions	2	5
Damage rate [displacements per atom per year (dpa/y) in stainless steel]	≥30	TBD
Nuclear heating rate (W/g in stainless steel)	≤54	≤70
Axial flux gradient over 200 mm	≤30%	14%
Available diameter (mm)	≥17	48
Available length (mm)	≥500	500

Table 1.2 (continued)

Parameter[a,b]	NSCANS goals	ANS conceptual design
Reflector vessel facility		
Fast flux	≥0.5	0.5
Fast:thermal ratio	≥1:3	1:13[f]
Number of instrumented positions	≥8	2[g]
Damage rate (dpa/y in stainless steel)	≥8	TBD
Nuclear heating rate (W/g in stainless steel)	≤15	18
Axial flux gradient over 200 mm	≤30%	16%
Available diameter (mm)	≥48	48
Available length (mm)	≥500	300[h]
Isotope production		
Transuranium production		
Epithermal flux	≥0.6	1.4
Epithermal:thermal ratio	≥1:4	1:3
Allowable peak heat flux (MW/m^2)	4	TBD
Total annual production:		
^{252}Cf (g)	1.5	1.7[i]
^{254}Es (μg)	40	60[i]
Epithermal-hydraulic rabbit tube		
Epithermal flux	Flux peak	1.0[i]
Epithermal:thermal ratio	position	1:4.9[i]
Allowable peak heat flux (MW/m^2)	≥1:4	1.75
	1.75	
Other isotope production facilities		
Thermal flux		0.9
Number of reflector positions	1	4
	≥4	
Number of thermal–hydraulic rabbit tubes		3
	3	
Materials analysis		
Activation analysis pneumatic tubes		4
40-cc rabbits in reflector	4	1
2-cc rabbits in reflector	1	0.3 (tube 1)
Thermal flux at reflector rabbit positions	≥0.2	0.06 (tubes 2,3, 4, and 5)[k]

Table 1.2 (continued)

Parameter[a,b]	NSCANS goals	ANS conceptual design
Heating rate		
Temperature in a 40-cc, high-density polyethylene rabbit (°C)	≤120	TBD
Rabbit tubes in light water pool	2	2
Thermal flux at light water rabbit positions	≥0.04	0.05; 0.02
Prompt-gamma activation analysis cold neutron stations		
Low-background (multiple-beam) guide system	1	1
Neutron-depth profiling		
Number of slant cold beams	1	1
Gamma irradiation facility in spent-fuel pool	≥1	1
Positron production position	1	1

EXHIBIT 16

Office of Energy Research

Energy Research Financial Assistance 94-02; Medical Application Program

AGENCY: U.S. Department of Energy (DOE).

ACTION: Notice inviting grant applications.

SUMMARY: The Office of Health and Environmental Research (OHER) of the Office of Energy Research (ER), U.S. Department of Energy announces its interest in receiving applications for conducting a Project Definition Study for the National Biomedical Tracer Facility (NBTF).

The NBTF is a large proton accelerator, with supporting facilities, to be utilized for the production, processing, and distribution of radioisotopes used in medical and industrial applications. The NBTF may be either a new facility or a modification to an existing facility. The mission of the NBTF is to: (1) Produce radionuclides for the nuclear medicine community; (2) conduct research in radioisotope production; and, (3) provide opportunities for education and training in radioisotope production.

The goals of the Project Definition Study will be to: (1) Further refine the design, construction schedule, and cost estimates associated with the NBTF; (2) examine the radioactive waste management, disposal, and other environmental issues associated with the NBTF; (3) develop a business plan for commercial operation of the NBTF over its expected lifetime (including reimbursement to the Government for its construction); and (4) assist DOE in deciding whether or not construction and operation of the NBTF would satisfy current and future radioisotope needs for medical and industrial applications and whether or not such a facility could be operated by the private sector. It is anticipated that DOE will approve up to five applications for funding project definition studies at approximately $300,000 each, contingent upon availability of Fiscal Year 1994 appropriated funds.

DATES: Formal applications submitted in response to this notice must be received by 4:30 p.m., E.S.T., February 1, 1994, in order to undergo a merit review, pursuant to 10 CFR part 600 and part 605, in March 1994 and to permit timely consideration for award in Fiscal Year 1994.

ADDRESSES: Formal applications referencing Program Notice 94-02 should be forwarded to: U.S. Department of Energy, Office of Energy Research, Acquisition and Assistance Management Division, ER-64, room E-220, Washington, DC 20585. Attn: Program Notice 94-02. The following address must be used when submitting applications by U.S. Postal Service Express mail, any commercial mail delivery service, or when hand carried by the applicant: U.S. Department of Energy, Office of Energy Research, Acquisition and Assistance Management Division, ER-64, 19901 Germantown Road, Germantown, Maryland 20874.

FOR FURTHER INFORMATION CONTACT: Dr. Robert Wood, Office of Health and Environmental Research, ER-73, U.S. Department of Energy, GTN, Washington, DC 20585. Telephone: (301) 903-3213. Potential applicants are required to contact Dr. Wood for supplementary information by November 15, 1993.

SUPPLEMENTARY INFORMATION: Following the award, each recipient will have up to 9 months from the date of the award to complete the NBTF Project Definition Study and to provide a report to DOE. On the basis of the information contained in the studies, an independent National Academy of Sciences evaluation of the need for the NBTF, and DOE's own analyses of all relevant considerations, the Department will decide whether construction and operation of the NBTF is required to satisfy the current and future radioisotope needs for medical and industrial applications. If the data supports the need for an NBTF, as well as the fact that such a facility can be operated economically by the private sector, additional Congressional funding will be sought.

The project description portion of an application must not exceed twenty (20) double-spaced pages.

In completing the project description portion of the application, each applicant must address in detail the following categories:

- Experience in design, construction, and operation of a large proton accelerator;
- Experience with large scale production of radioisotopes including target chemistry, radioisotope processing, hot lab operation, waste disposal operations, or evidence that expertise can be obtained;
- Qualifications for establishing a radioisotope distribution network, packaging, and transportation;
- Experience in conducting research on radioisotope targetry, separations, purification, and in the development of improved production technology;
- Familiarity with Federal, State, and local regulations required for siting, construction, and operation of the facility;
- Proven capability to provide an educational program in radiochemistry and a research program in nuclear medicine. Demonstrated capability in nuclear medicine research and in education and training, or evidence that such capabilities can be obtained. If a broad research and education component to the NBTF is recommended by the Institute of Medicine, such information will be requested later in the competition process.

More information about the development and submission of applications, eligibility, limitations, evaluation, selection process, and other policies and procedures may be found in 10 CFR part 605, the Energy Research Merit Review System (58 FR 10244) and the Application Guide for the Office of Energy Research Financial Assistance Program. The application guide is available from the Office of Health and Environmental Research, ER-73, Department of Energy, GTN, Washington, DC 20585. Telephone requests may be made by calling (301) 903-3213.

The Catalog of Federal Domestic Assistance Number for this program is 81.049.

Issued in Washington, DC, on October 8, 1993.

James F. Decker,

Acting Director, Office of Energy Research.

[FR Doc. 93-25240 Filed 10-13-93; 8:45 am]

BILLING CODE 6450-01-P

EXHIBIT 17

NATIONAL BIOMEDICAL TRACER FACILITY
PROJECT DEFINITION STUDY
Supplemental Information

A. Background/History

For more than 2 decades, the Los Alamos Meson Physics Facility, Los Alamos National Laboratory, and the Brookhaven Linac Isotope Producer, Brookhaven National Laboratory, have been used to produce radioisotopes for clinical applications and medical research. Both facilities are high-energy accelerators which are funded for physics research by the Office of High Energy and Nuclear Physics. Isotope production at both facilities operates in a parasitic mode to the existing accelerators. Funding constraints during the mid 1980s necessitated reduced operating schedules for both accelerators. For part of the year neither facility operated resulting in a lack of a continuous supply of high-energy accelerator-produced radioisotopes. In response to the shortage of radioisotopes, a workshop was held in 1988 at Los Alamos National Laboratory to address this issue. From that workshop, a recommendation was made to the Department of Energy (DOE) to construct a dedicated high-current accelerator for radioisotope production (Proceedings of the DOE Workshop on *The Role of a High-Current Accelerator in the Future of Nuclear Medicine*, 1989).

In recognition of the need for a continuous supply of high-energy accelerator produced radioisotopes, DOE provided under Grant Number DE-FG05-91ER61131 a grant in February 1991 to the Society of Nuclear Medicine (SNM) to conduct a Planning and Feasibility Study of the National Biomedical Tracer Facility (NBTF). The report from this Study was completed in April 1991 and submitted to Congress by DOE in June 1991. The NBTF Planning and Feasibility Study identified the general characteristics and requirements of the NBTF which were not site specific. The mission of the NBTF as described in the *Proceedings of the Purdue National Biomedical Tracer Facility Workshop*, 1992 are as follows:

- Production of radioisotopes for the biomedical and scientific communities.
- Conduct research into radionuclide production, separation, and purification.
- Provide for education and training in techniques of radionuclide production, separation and purification; radiotracer synthesis; radiation protection and safety; and the application of radiotracer methodologies (under review by the Institute of Medicine).
- Conduct research in basic radiopharmaceutical chemistry which fosters and supports the continued development of biomedical applications of radiotracer methodologies (under review by the Institute of Medicine).
- Produce radionuclides for commercial purposes in cases where these radionuclides are not adequately available to meet national needs through existing commercial channels.

To further define the NBTF, Congress directed DOE to fund a Project Definition Study of the NBTF in Fiscal Year 1994. In response to this Congressional direction, DOE recently issued a Notice for the NBTF Project Definition Study in the October 14 issue of the *Federal Register*. The goals of the NBTF Project Definition Study will be to: (1) further refine the design, construction schedule, and cost estimates associated with the NBTF; (2) examine the radioactive waste management, disposal, and other environmental issues associated with the NBTF, and (3) develop a business plan for the commercial operation of the NBTF over its expected lifetime (including reimbursement to the Government for its construction).

Concurrent with the NBTF Project Definition Study, the Office of Health and Environmental Research has requested the Institute of Medicine to independently assess the need for an NBTF and to provide advice on the scope of the project. The goals of the Institute of Medicine study are to: (1) provide guidance on the selection criteria for the NBTF Project Definition Study awards — completed and included in the Notice mentioned above, (2) evaluate current and future needs for isotopes produced by large proton accelerators and the capability to produce these radioisotopes, (3) determine the priority of the NBTF in light of the research and clinical importance of the radioisotopes produced, alternative production capabilities, and other nuclear medicine opportunities, (4) determine the research and training needs associated with the NBTF, and (5) provide guidance on the evaluation criteria for the NBTF Project Definition Study reports.

Following the completion of the NBTF Project Definition Study, the Department will consider the Institute of Medicine's Study recommendations and the information contained in the NBTF Project Definition Study reports to assess whether to seek funding for the NBTF. If the decision is made to seek support, the information contained in the NBTF Project Definition Study reports will also be used to evaluate whether the private sector will be able to construct and operate an NBTF in an economically viable manner. If it is determined that the private sector is not likely to achieve a sales level necessary to operate the facility, the Department may elect to seek funding to place the NBTF at a National Laboratory.

B. NBTF Project Definition Study Application

Applicants applying for the NBTF Project Definition Study grant must include the following items under the project description portion of the application:

- **Discuss your experience in design, construction, and operation of a large proton accelerator.**
- **Discuss your experience with large scale production of radioisotopes including target chemistry radioisotope processing, hot lab operation, waste disposal operations, or evidence that expertise can be obtained.**
- **Provide qualifications for establishing a radioisotope distribution network, packaging, and transportation.**
- **Discuss your experience in conducting research on radioisotope targetry, separations, purification, and in the development of improved production technology.**
- **Discuss your familiarity with Federal, State, and local regulations required for siting, construction, and operation of the facility.**
- **Discuss your capability to provide an education and training program in radiochemistry and related areas, experience in nuclear medicine research, or provide evidence that such capabilities can be obtained.**

C. NBTF Project Definition Study Report

Each applicant receiving an NBTF Project Definition Study award (hereinafter "Grantee") must include the following items in the NBTF Project Definition Study report:

- A narrative discussion and sketch for a large proton accelerator to produce radioisotopes for medical and research purposes. This should include a description of the type of accelerator, the proton beam energy, and the proton beam current of the proposed accelerator. "Suggested" characteristics of an NBTF accelerator as described in the *NBTF Planning and Feasibility Study of the National Biomedical Tracer Facility Report*, 1991, and the *Proceedings of the Purdue National Biomedical Tracer Facility Workshop*, 1992, are as follows:

  (1) the accelerator may be a linear accelerator (Linac) or cyclotron

  (2) the extracted proton beam energies should range from 30 to 100 MeV step size

  (3) the energy should be reproducible to 1%

  (4) the beam energy spread should be < 1%

  (5) the beam current should be >0.75 mA, with an expectation of achieving 1.0 mA

  (6) the accelerator should provide two high-intensity beams and two low-intensity beams, at least two of which can be operated simultaneously with separately controllable energies

  It is requested that the Grantee review the suggested characteristics for the NBTF accelerator and provide justification for these characteristics and any changes proposed.

- Provide a narrative discussion and sketch for the radioisotope production facility. This should include a specific design of the target facility(s) and associated radioisotope separation facility(s) (hot cells). Specific items such as, the number of beam lines, the energy of the beams lines, and the utilization of existing facilities/equipment should be included. The number and design of the targeting facilities should adequately meet the expectations as reported in the *NBTF Planning and Feasibility Study of the National Biomedical Tracer Facility Report*, 1991 and the *Proceedings of the Purdue National Biomedical Tracer Facility Workshop*, 1992. Provisions should also be included for the incorporation of radiochemistry laboratories meeting Good Laboratory Practice (GLP) standards. It is requested that the Grantee also provide justification and rationale for the proposed target facility design.

- Develop preliminary cost estimates for the design and construction of the NBTF. Include construction schedules for the accelerator and the associated radioisotope production facilities. Discuss potential for construction cost-sharing by non-Federal partners.

- Describe all Federal, State, and local permits required to construct and operate the NBTF. This should include cost estimates and time schedules for obtaining these permits.

- Develop a detailed plan for handling, storage, and disposal of radioactive wastes generated by the NBTF. Include in your discussion, the types of radioactive waste generated, estimated quantity and half-lives involved, and Federal, State, and local regulatory requirements.
- Provide a business plan for the operation of the NBTF. Include and fully describe:

  (1) anticipated sales of isotopes and identify potential purchasers

  (2) expected annual income from sales

  (3) all costs of operation associated with the facility

  (4) annual costs of waste removal

  (5) plan for reimbursing the Government for its contribution for the NBTF

  If the total projected income is insufficient to cover operating costs, provide a method to avoid or recover these costs.

- Provide a detailed plan for operating the NBTF. It was suggested in the *NBTF Planning and Feasibility Study of the National Biomedical Tracer Facility Report*, 1991 and the *Proceedings of the Purdue National Biomedical Tracer Facility Workshop*, 1992, that the facility should operate 24 hours/day, 7 days/week for a minimum of 42 weeks/year. It was also suggested that a normal operation/maintenance schedule could be 3 weeks of continuous accelerator operation followed by one 8-hour maintenance shift.
- Provide a detailed discussion on the types of proposed radioisotopes to be produced annually, the quantity of radioisotopes produced annually, production schedules, priorities, and any planned collaborations. The following radioisotopes were suggested in the *Proceedings of the Purdue National Biomedical Tracer Facility Workshop*, 1992.

  ^{7}Be ^{28}Mg ^{47}Sc ^{48}V ^{55}Co ^{57}Co ^{62}Zn
  ^{64}Cu ^{67}Cu ^{68}Ge ^{73}As ^{76}Br ^{77}Br ^{80m}Br
  ^{82}Sr ^{88}Y ^{89}Zr ^{95m}Tc ^{96}Tc ^{97}Ru ^{109}Cd
  ^{114m}In ^{122}Xe ^{124}I ^{127}Xe ^{128}Ba ^{195m}Au ^{203}Pb
  ^{205}Bi ^{206}Bi ^{207}Bi ^{235}Np ^{236}Np ^{237}Pu

  It is requested that each Grantee review this list of candidate radioisotopes and provide justification for their need and also evaluate the needs for additional radioisotopes.

- Discuss your ability to provide an education and training program in radiochemistry and related areas or provide evidence that such capabilities can be obtained. Discuss potential for conducting research and training in the areas of target design, radiochemistry, etc.

E. NBTF Reference Material

- Proceedings of the DOE Workshop on *The Role of a High-Current Accelerator in the Future of Nuclear Medicine*, 1989.
- Society of Nuclear Medicine's *National Biomedical Tracer Facility Planning and Feasibility Study*, 1991.
- *Proceedings of the Purdue National Biomedical Tracer Facility Workshop*, 1992.

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Exhibit 18

United States Government **Department of Energy**

memorandum

DATE: JUL 29 1993

REPLY TO ATTN OF: PR-132 (Barnes, 6-8684)

SUBJECT: Business Strategy Development for the National Biomedical Tracer Facility (NBTF)

TO: Director, Acquisitions and Assistance Management Division (ER-64)

Pursuant to your memorandum dated June 3, 1993, same subject, a business strategy group was convened to consider near-term options as to how to proceed with the NBTF acquisition. The report of that group is attached for disposition as you see fit. We hope the report proves to be of benefit.

Bob Barnes

Robert E. Barnes, Director
Field/Headquarters Support Division
Office of Procurement and Assistance
Management

Attachment

cc w/Attachment:
Robert Forst, GC-34
Michael Saltzman, CR-143
Jerry Zimmer, CH

REPORT OF THE BUSINESS STRATEGY GROUP FOR THE NATIONAL BIOMEDICAL TRACER FACILITY PROGRAM

JULY 29, 1993

INTRODUCTION

By letter dated June 3, 1993, the Director of the Acquisitions and Assistance Management Division (ER-64) of the Office of Energy Research established a Business Strategy Group (BSG) to make recommendations on how to proceed toward acquisition of a National Biomedical Tracer Facility (NBTF). The BSG included representatives of the Office of Procurement and Assistance Management; Office of the Chief Financial Officer; General Counsel; and the Chicago Operations Office. The BSG met on June 16, 1993, and received a presentation on the NBTF program background, status, and recommended approach from representatives of the Office of Energy Research. This report documents the recommendations of the BSG.

BACKGROUND

The Los Alamos Meson Physics Facility and the Brookhaven Linac Isotope Producer facility currently produce radioisotopes for distribution through the Nuclear Energy Office of Isotope Production and Distribution Program. The Energy Research Office of Health and Environmental Research also provides support for research activities utilizing these radioisotopes. Core support for the Brookhaven Linac Isotope Producer and the Los Alamos Meson Physics Facility is provided by the Office of High Energy and Nuclear Physics. In the late 1980s, budget limitations curtailed the operation of these accelerator facilities, and the nuclear medicine community became concerned about the lack of a continuous domestically produced supply of certain radioisotopes. This concern has been increased with the planned shutdown of the Los Alamos Facility in fiscal year 1994.

A workshop was convened by the Department in 1988 to address this concern, and a report was issued which recommended that the Department support a dedicated biomedical facility, the National Biomedical Tracer Facility. In 1991, a Department-funded report by a task force of the Society of Nuclear Medicine and the American College of Nuclear Physicians made this same recommendation. Although a definitive cost figure for the National Biomedical Tracer Facility must await completion of the Project Definition Phase, knowledgeable Departmental staff estimate this will exceed $100 million. At present, the fiscal year 1994 budget contains $2 million for the Project Definition Phase studies to further define the specifics of the National Biomedical Tracer

Facility. In addition, the Department has also requested funds in the fiscal year 1994 budget for upgrade of the Brookhaven Linac Isotope Producer facility. Initial production estimates suggest that the upgraded facility would meet most, but not all of the projected high energy accelerator-produced isotope needs in the country.

The Office of Nuclear Energy's Isotope Production and Distribution program has a substantial interest in the production and distribution of radioisotopes from the National Biomedical Tracer Facility through their Inventory Account. The Office of Energy Research, under the nuclear medicine research program, has an interest in supporting research activities that would involve development of new radiolabeled compounds for potential applications in diagnosis and therapy. Although the Department had determined that the Project Definition Phase study should be included in the programs of the Office of Nuclear Energy, Congress directed that this effort would be funded under the Office of Energy Research's Biological and Environmental Research category. The strong Congressional interest in the National Biomedical Tracer Facility is also evidenced by their direction that the 1991 report by the Society of Nuclear Medicine be funded by the Department, and by several Congressional Hearings at which the Society has been asked to present their support for the Facility.

The Department is currently proceeding with an Institute of Medicine study which will evaluate the need for a National Biomedical Tracer Facility and will also evaluate criteria for review of applications to conduct the Project Definition Phase studies. It is anticipated that requests for applications will be prepared and published in the Federal Register by October 1, 1993, for the Project Definition Phase studies to start and be completed within a year.

ASSUMPTIONS

The alternatives discussed in this report are premised on the following assumptions:

- Purpose of the Facility -- Information presented to the BSG strongly suggests that the raison d'etre for the NBTF is isotope production. Although we recognize that training and research would also be conducted at such a facility, information presented to the BSG indicates that these goals are incidental to the primary mission of isotope production for medical diagnostics purposes. To state it another way, if isotope production were removed, the training and research missions are not high enough priorities to justify the expenditures on such a facility, and the facility would not be built. Therefore, the overall strategy should be geared to isotope production.

- Need for the Facility -- Although data presented to the BSG indicate that 98% or more of the U.S. requirements for isotopes for nuclear medicine applications could be satisfied with the planned upgrade of the Brookhaven Linac Isotope Production (BLIP) facility alone, this report is based on the supposition that the new NBTF is deemed to be necessary and will be built. The BSG questions, however, the prudence of pursuing construction of a $100 million facility to satisfy approximately 2% of the isotope requirements not satisfied by the BLIP upgrade (which will likely occur whether or not the NBTF is built.) It appears, moreover, that the remaining 2% might be available internationally if the NBTF were not built.

KEY ISSUE

The BSG believes that the key question yet to be adequately addressed is whether it is commercially feasible to operate the proposed facility on a self-sustaining basis. The BSG believes that the answer to that question essentially dictates whether the facility (if it should be built at all) should be built and operated by a national laboratory, or by an entity from the private sector.

If the facility is commercially viable, the BSG believes the facility should be built and operated by the private sector with any Government assistance (grant or cooperative agreement) provided through competitive techniques. The national laboratories should not be involved (except perhaps in some supporting role to assist in facilitating the competition.) If the facility is not commercially viable, but should be built as a matter of public policy, it appears to fit well with the mission of several of the national laboratories. From a purely pragmatic point of view, the BSG believes there are significant advantages -- both technical and economic -- to building and operating the facility under the auspices of a national laboratory. Among the more important of these advantages is the laboratories' experience in handling the high level radioactive wastes expected to be generated by the facility and possession of land and facilities on which to construct and operate such a facility. Furthermore, with the diminution of work at these and other laboratories, and the Department's commitment to divert displaced workers to other projects to the maximum extent possible, the BSG believes that, building the facility at a national laboratory would help fulfill these personnel policies.

In summary, if the facility is commercially viable, we believe the facility should be placed competitively in the private sector; if the facility is not commercially viable, it fits well with the mission of, and should be placed at a national laboratory.

Obviously, then, the question of commercial viability is key to the strategy for acquiring the NBTF and demands careful consideration. However, the information presented to the BSG (including the March 1991 feasibility by the Society of Nuclear Medicine) contains insufficient data to draw a supportable conclusion in this regard. In view of the above, the BSG concludes that the next step in the process should be to assess the commercial potential of the NBTF in a quick, but comprehensive, and unbiased manner.

ALTERNATIVES

The BSG considered several alternative approaches to accomplishing the recommended assessment of commercial viability. These are discussed below:

- Office of Energy Research Proposed Approach -- At the time of the BSG presentation, the Office of Energy Research (ER) representative presented a proposal which calls for simultaneous solicitation of applications to conduct program definition studies from both private industry/educational institutions and the national laboratories. Although these studies would include a "business plan" for operation of a NBTF, most of the study would be devoted to preliminary designs for the accelerator and isotope production facility, cost estimates, and siting information. For the reasons outlined above, the BSG believes this approach is premature. Furthermore, it essentially places the national laboratories and the private sector in direct competition. We believe the commercial viability study discussed above needs to be done first. Based on the results of that effort, project definition plans should then be solicited from either the private sector or the national laboratories, but not both.

The following relate to alternatives for conducting the recommended commercial viability study:

- Independent Scientific Body Study -- The study might be conducted by a independent scientific body of national renown such as the National Academy of Science. This has the advantage of coming from a source of impeccable integrity that is beyond reproach. Such a body probably does not have, but possibly could acquire the type of expertise necessary to conduct a business oriented study such as envisioned here. This may be the fastest approach; however, the National Academy of Science may not be willing to accept this task.

- Independent National Laboratory Study -- The study might be obtained through one of the national laboratories not directly involved in isotope production issues. This has the advantage of being relatively quick to do, but has several drawbacks. First, such a laboratory would have neither the technical expertise in isotope production nor the business acumen to perform such a study. Furthermore, it could be argued that any national laboratory could have a bias toward the national laboratory alternative.

- Private Sector Third Party Study -- The study could be done through a disinterested third party in the private sector. This has the advantage of being perhaps the most credible source, as well as the most flexible in terms of being able to obtain the "right" expertise to conduct a business oriented study. There are many consulting firms that provide such services routinely. One possible disadvantage is the time necessary to competitively select a source. However, this might be overcome by a non-competitive award to an 8(a) firm.

RECOMMENDATION

For the reasons discussed above, the BSG recommends that the Office of Energy Research proceed to quickly obtain a study of the commercial viability of the proposed NBTF, from either an independent scientific body or an 8(a) firm. Based on the results of that study, full proposals to build and operate the NBTF might then be competitively solicited from private sector firms and educational institutions or, if it is determined that commercial viability does not exist, DOE could choose from among the national laboratories which potentially or actually are involved in isotope production.

EXHIBIT 19

BROOKHAVEN NATIONAL LABORATORY
ASSOCIATED UNIVERSITIES, INC

Upton, Long Island, New York 11973

(516) 282 3391
FTS 666 FAX: 516-282-3407

Office of the Director

November 23, 1993

The Honorable Michael Synar
Chairman
Subcommittee on Environment,
Energy, and Natural Resources
2157 Rayburn House Office Building
Washington, DC 20515-6143

Dear Congressman Synar:

This letter is in response to your query of November 12, 1993 concerning information on Brookhaven National Laboratory's (BNL) currently planned and potential capabilities for research and production of radioisotopes. Our responses to your specific questions follow. They were developed by Leonard Mausner and Suresh Srivastava of the Medical Department after consultation with the staff of the Alternating Gradient Synchrotron Department and the Plant Engineering Division.

1a) The purpose of the BLIP (Brookhaven Linac Isotope Producer) upgrade project is to reverse the erosion in radioisotope production capability and availability that has occurred at BNL and Los Alamos, and to position BLIP to pick up the slack should the LAMPF (Los Alamos Meson Physics Facility) shut down. This effort is not a substitute for the National Biomedical Tracer Facility (NBTF). We plan to increase the production levels of our presently produced isotopes and add to our list the four most important isotopes that are presently made only at LAMPF (ie., ^{88}Y, ^{22}Na, ^{109}Cd, ^{73}As). To improve production, the Linac (linear accelerator) beam current will be increased from a maximum of 60 microamp to 145 microamp, and to improve research capability we will provide beam energy varying from 60-200 MeV in 22 MeV increments. However, much of the Linac upgrade cost is to address reliability and safety issues, not increased intensity. Finally, to improve isotope supply we propose to run the facility up to 46 weeks per year with 90% beam availability (1.5 d/month maintenance = 5% + 5% downtime). This compares to an average of 20 weeks per year at ~50 microamp, at 84% availability.

A summary of our projected isotope production capability is contained in Table 1. Increased throughput due to higher beam intensity plus the inherent flexibility of the BLIP target system will give us this capability. We do not plan to add to our list every isotope presently produced at LAMPF nor any of the additional isotope envisioned for

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the NBTF. It may be possible to produce small quantities of some of these isotopes if the required radiochemistry staff can be added. Since in the early stages of most research projects only small quantities of radioactivity are required, the primary limitation to providing a larger menu of isotopes for research is the radiochemistry staff needed to develop targetry and processing procedures, and secondarily, limitation is laboratory/hot cell space to work. However, substantially increasing the production level or the frequency of production of an existing isotope would involve trade-offs, that is, making small quantities of other isotopes.

1b) The Radionuclide and Radiopharmaceutical Research Group of the Medical Department at BNL operates the BLIP. This group's budget, including personnel and sources of support for Fiscal Year 1993 and projections for Fiscal Year 1994 are given in Table 2. Some non BLIP isotope research work is included in these totals but cannot be easily separated since the staff and equipment are shared. Notice that the projected FY 94 levels are reduced considerably, and will require readjustment.

1c) As summarized in Table 3, the total operating cost for BLIP Upgrade for Fiscal Year 1996 is estimated to be $5.57 million. There is also a need for $629K of capital equipment (mostly analytical instrumentation). We project radioisotope sales revenues ranging between $1.5 - 3.2 million. Operating costs not offset by sales revenues will have to be shared by the Office of Health and Environmental Research (OHER) and/or the Office of Isotope Production and Distribution (IPD/NE) of DOE. At this point there is no commitment by either to supply these funds. It should also be noted that after 1997 there may be additional users of the Linac e.g., RHIC (Relativistic Heavy Ion Collider) and a proton therapy program that will share running costs with BLIP. Thus the BLIP operating economics may improve a year or two after the completion of the BLIP upgrade.

1d) Further upgrades to BLIP and the Linac beyond that provided in the current FY '94 authorization are feasible. The beam current could be increased to 270 microamp. Improvements to the BLIP target cooling systems, control system and radiation shielding could also be implemented to handle this intensity. The research capability could be enhanced by providing proton energy tunability from 66-200 MeV in 2 MeV increments. It does not, however, appear cost effective to incrementally renovate and expand the existing archaic Hot Laboratory Facilities. Rather, we propose to convert much newer space in the Medical Department into a modern radioisotope laboratory. This is the largest cost item in the budget. An estimate of construction and operation costs for fiscal year 1997 is summarized in Table 4. The total is $10.53M an with annual operating cost of $7.8M. While we are fairly confident that Linac operation at an average current above 270 microamp is feasible, cost estimates for upgrades beyond 270 microamp will require a further detailed study, since they involve too large an extrapolation from our present parameters.

2a) A comparison of the isotope production capability of the authorized BLIP Upgrade and that as envisioned for the NBTF is contained in Table 1. With at least 5 times more beam, the NBTF offers much better yield for large volume isotopes e.g., ^{82}Sr. Additionally, the higher beam current should lead to higher specific activity (mCi/mg), which is important in certain situations, such as labeling monoclonal antibodies with ^{67}Cu, and ^{22}Na for positron spin resonance studies. The NBTF can do much better. Also, the higher beam intensity at NBTF will allow improved cost efficiency and greater overall throughput. The NBTF will initially produce 12-14 of the same isotopes as BLIP will. However, NBTF will ultimately be capable of producing at least twice as many isotopes. Another practical difference is that relative to BLIP the new machine in the NBTF should offer improved reliability, improved power utilization and reduced manpower needs and thus lower costs for operation.

The NBTF mission is considerably broader in scope than that presently planned for the BLIP Upgrade. The BLIP Upgrade assumes no significant enhancement of research and educational capability except restoration to the FY 92 level support (~9 FTE). The NBTF is planned to have at least one precision beam line, tunable from 30-100 MeV in 1 MeV increments. It should operate simultaneously with the production beam lines, essentially invisible to the production effort. Upgraded BLIP will have one research beam line tunable from 66-200 MeV in 21 MeV increments, and it must alternate operation with the production line. However, this is not anticipated to happen often enough to significantly impact production.

The Radionuclide and Radiopharmaceutical Research Program has engaged in a limited educational and training role over the years. This consists of training post-doctoral fellows (~1.5/yr) and undergraduate students (~1/yr), hosting guest scientists and collaborators, and participating as faculty for the annual BNL Summer School in Nuclear Chemistry. The latter is jointly sponsored by the American Chemical Society and DOE. In contrast, the NBTF with a proposed total staff in excess of 44, is to have a full time training coordinator, 3 post-doctoral fellows, 6 graduate students, plus several undergraduates.

2b) An increase in BLIP beam intensity the 270 microamp should, in turn, increase the capability to produce ^{82}Sr to 70% of the projected annual demand, and ^{67}Cu to 100% of the projected 1997 demand. The production of other isotopes on the BLIP list would benefit from improved specific activity. Augmented staff and laboratory facilities will expand the BLIP list of isotopes for research. As the demand for most of these is unknown, we cannot speculate on the fraction of the total isotope requirements that BLIP could serve, compared to the NBTF. An additional radiochemist (PhD), two radiochemistry technicians, two post-doctoral fellows and two graduate students are considered reasonable for an enhanced level of production, research and training. This would also allow the BLIP program to respond to outside requests for new isotopes. To date, our research resources have not allowed this role, but it is highly desired by the nuclear medicine research community. Outside proposals would be reviewed for scientific merit and compatibility with available resources by a BLIP Users Advisory Committee that would report directly to me.

3a) The DOE solicitation for the NBTF does not specify any particular type of accelerator or operational parameters. However, an internal BNL Task Force, the NBTF Planning and Feasibility Study prepared by The Society of Nuclear Medicine and the American College of Nuclear Physicians, and the NBTF Workshop at Purdue University, all recommend a cyclotron with 100 MeV energy and about 750 microamp beam current. BNL personnel participated in these studies. We consider such a facility feasible. Several commercial accelerator vendors appear capable of building the machine, but none presently have experience at the proposed high energy and high current. Problems of cost and schedule could therefore occur in extrapolating from the vendor's present lower energy and lower current designs. A significant unresolved design issue concerns the ability of production targets to dissipate the very large amount of beam power that the NBTF will deliver (>75 kW). Research and development work on target design will thus have to be part of the NBTF construction project (BLIP upgrade could begin to address this issue). Also, the NBTF will produce considerably more radioactive waste, so this issue needs careful examination, as was noted in the DOE solicitation. At present, certain categories of radwaste cannot be disposed of and must be stored on site. Finally, we are skeptical of the prospects for commercial viability of the NBTF as required in the DOE solicitation.

3b) BNL had no role in the preparation of DOE's NBTF solicitation. The requirements in this document preclude a BNL response.

3c) BNL is, however, interested in developing an NBTF proposal. All the experience and expertise listed in the NBTF solicitation already exists at BNL. An estimated $350,000 would be required to prepare an NBTF conceptual design report.

I hope this information is of use for your upcoming subcommittee hearing. We are prepared to provide more data on any specific topic as necessary.

Sincerely,

Richard B. Setlow

Richard B. Setlow Ph.D.
Associate Director of Life Sciences

encl.
sc

Exhibit 20

(sample of letter to Washington
State delegation and Governo

The Secretary of Energy
Washington, DC 20585

December 6, 1993

The Honorable Patty Murray
United States Senate
Washington, D.C. 20510

Dear Senator Murray:

The Department of Energy has concluded its review of the report, "Future Use of the United States Department of Energy's Fast Flux Test Facility," dated September 20, 1993. The report, a product of the Independent Review Team commissioned by the Department to evaluate a multimission role for the Fast Flux Test Facility, details the business potential, net revenues, policy issues, risks, and benefits associated with a number of current and potential facility missions. We believe the report represents a comprehensive and objective evaluation of the capabilities of the Fast Flux Test Facility and the potential missions which the facility could successfully support.

The report concludes that there is no combination of missions for the Fast Flux Test Facility that has a reasonable probability of financial viability over the next ten years and recommends that the facility be shut down, provided the Department's remaining facilities have the capability to carry out the various missions they will be expected to perform. We have reviewed the capabilities of the Department's remaining facilities and have concluded that the Fast Flux Test Facility is not required to support the Department's missions.

We concur with the report's conclusion and recommendation and plan to commence on December 15, 1993, a phased process to place the Fast Flux Test Facility in a radiologically and industrially safe shutdown condition. We expect the Fast Flux Test Facility employees to be transitioned to other jobs involving environmental restoration of the Hanford Site.

We appreciate the support you have given to the Fast Flux Test Facility and look forward to continuing to work together for the environmental restoration of the Hanford Site.

Sincerely,

Hazel R. O'Leary

Exhibit 21

The Secretary of Energy
Washington, DC 20585

December 3, 1993

The Honorable Mike Synar
Chairman
Subcommittee on Environment,
Energy, and Natural Resources
Committee on Government Operations
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your letter of October 25, 1993, concerning the Department of Energy's practices and policies on the production and sale of isotopes in competition with commercial distributors, including domestic and foreign suppliers.

Our responses to your questions are enclosed. This reply has been coordinated with the Office of the United States Trade Representative.

The Department believes that its efforts to use the reactors, accelerators, and other unique facilities in its complex for isotope production and distribution are in full accord with the governing provisions of the Atomic Energy Act, applicable policies, and international agreements. Moreover, such use of the Department of Energy capabilities is fully supportive of the national interest as well as the medical, economic, and environmental objectives of the Clinton Administration.

Your interest in the Department's Isotope Production and Distribution Program is appreciated.

Sincerely,

Hazel R O'Leary

Hazel R. O'Leary

Enclosure

cc:
The Honorable J. Dennis Hastert
Ranking Minority Member

The Honorable Michael Kantor
United States Trade Representative

U.S. Department of Energy

Practices and Policies for Competing with
Foreign and Domestic Isotope Suppliers

Reference: Congressman Synar's letter dated October 25, 1993, to Secretary O'Leary and Trade Representative Michael Kantor

Question 1:

Describe the Department's current practices and policies for competing with (i) domestic suppliers and, (ii) foreign suppliers of stable isotopes and both accelerator-produced and reactor-produced radioisotopes. Identify the statutory and regulatory bases for such practices and policies.

Answer:

A. Current Practices and Policies

The Department's current practices and policies for competing with domestic and foreign suppliers of radioisotopes are established in the 1965 Policy Statement of the Atomic Energy Commission, entitled "Policies and Procedures for Transfer of Commercial Radioisotope Production and Distribution to Private Industry" (Federal Register, Tuesday, March 9, 1965). The Policy states that the Government will refrain from competing with private sources of materials when they are reasonably available commercially.

The Policy Statement provides both procedures for the Department's voluntary withdrawal of radioisotopes from markets, and withdrawal based upon evidence that markets are being adequately supplied, following petition by a private producer.

The Policy Statement is applicable to both accelerator-produced and reactor-produced radioisotopes. Neither the Department nor its predecessors formally adopted a policy with respect to stable isotopes. As was testified at the August 12, 1992, hearing before the Subcommittee on Environment, Energy, and Natural Resources, at the request of a private stable isotope producer, the Department agreed to employ the procedures and criteria provided in the Policy Statement in the resolution of a withdrawal petition on stable isotopes. That petition was ultimately denied when the Department ascertained from the affected stakeholders (customers) that supplies of the materials were not reasonably available.

Under the Policy Statement, no distinction is made between domestic and foreign sources, either as petitioners or producers and suppliers, provided that foreign sources may be accepted in assessing the effectiveness of competition only when they are actively marketing the isotopes in the United States.

B. Statutory Basis for Practices and Policies

The Atomic Energy Act of 1954 does not include a specific statutory basis for the 1965 Policy Statement. Rather, it established the U.S. Government as the initially exclusive domestic developer of atomic energy and encouraged it, acting through the Atomic Energy Commission, to undertake activities that could lead to the potential development of future commercial, civilian markets for atomic energy products and services.

No target dates were provided for the development of such markets and no procedures or criteria were furnished on which withdrawal decisions could be based. Decisions concerning atomic energy markets were left, instead, to the expertise and discretion of the Commission and its successor agencies, the Energy Research and Development Administration and, later the Department of Energy, with the caveat that their activities should conform to the generic U.S. policy of strengthening free competition in private enterprise. In the 1965 Policy Statement, the Commission declared its intention to refrain from competition with private sources capable of producing and processing radioisotopes and provided the criteria for use in carrying out what it perceived to be its responsibility under the Atomic Energy Act. The Policy Statement has been extended in one case, noted above, to a withdrawal request involving a distributor of stable isotopes.

Key statutory provisions of the Atomic Energy Act that relate to the Department's production and distribution of isotopes are:

- Section 53, which authorizes the domestic distribution of special nuclear materials to qualified applicants at reasonable prices. Section 53f. specifically directs the Department to distribute sufficient special nuclear material within the United States to permit the conduct of widespread independent research and development activities to the maximum extent practicable and directs that, in the event applications exceed the amount available, preference is to be given to those activities most likely, in the Department's opinion, to contribute to basic research, to the development of peacetime uses of atomic energy, or to the economic and military strength of the Nation.

- Section 81, which authorizes the Department to distribute by-product materials to qualified applicants, with or without charge. Material distributed for a charge must be priced on an equitable basis that, in the Department's opinion, will (a) provide reasonable compensation to the Government for the material, (b) not discourage the use of the material or the development of sources of supply of the material independent of the Department, and (c) encourage research and development. Further, Section 81 requires the Department to give preference in distributing by-product material to applicants that propose to use it in either the conduct of research and development or in medical therapy.

- Section 54, which authorizes the foreign distribution of special nuclear materials.
- Section 161m., which authorizes the processing, fabricating, separating or refining in the Department's facilities of source or byproduct material and other material not defined as special nuclear material and the distribution of such materials to licensees.

Question 2:

Describe how Canadian radioisotope producers and products are defined and treated under both existing U.S.--Canadian trade agreements and NAFTA.

Answer:

Canadian produced radioisotopes are not accorded special treatment under either the U.S.--Canada Free Trade Agreement or NAFTA. All of the provisions relating to trade in goods under these agreements apply. Generally speaking, under these agreements, Canadian produced radioisotopes are to be treated no differently than U.S. produced radioisotopes.

Question 3:

Describe how the Department's activities to produce and market molybdenum-99 utilizing the Omega West Reactor are consistent with the policy, statutory and treaty interpretations identified in Items 1 and 2.

Answer:

Basis for Department of Energy Production of Molybdenum-99

A decision by the Department to produce and market molybdenum-99, and other medical isotopes utilizing the Omega West Reactor would be consistent with the policy and statutory interpretations identified in the response to questions 1 and 2 above for the following reasons:

- Nordion International of Canada is the sole supplier of approximately 90 percent of all radioisotopes used in the United States, including the widely used and critically important medical isotope, molybdenum-99. This isotope is the parent of technetium-99m which is utilized in more than 30,000 procedures per day in the United States. One out of every three hospital patients has a nuclear medicine procedure of some type.

  Nordion International, through its production arrangement with Atomic Energy of Canada Limited, is clearly a viable isotope supplier. However, there have been instances when the U.S. market for radioisotopes such as molybdenum-99 has been threatened with curtailment due to technical difficulties and labor problems of

Atomic Energy of Canada. In fact, we understand that Atomic Energy of Canada recently has permanently shut down one of its two production reactors, contrary to previous expectations. Dependence on a single reactor is undesirable.

- Under the Policy Statement, the Department's withdrawal or inactivity in a market would be acceptable only if there were assurances that the private producer(s) would continue their production in a manner that would not adversely affect the public interest. Because the half-lives of most of these isotopes, including molybdenum-99, are numbered in hours or days, supply interruptions of even short duration would be adverse to the national interest.

At the request of Atomic Energy of Canada/Nordion, the Department of Energy Isotope Production and Distribution Program has performed studies to evaluate the feasibility of performing backup irradiation of Canadian supplied isotope targets in U.S. reactors and the transport of irradiated targets to Canada for processing. These studies considered U.S. Department of Energy reactors at Oak Ridge, Los Alamos, and Sandia. The studies concluded that this was not a technically or economically feasible solution. Thus, a standing capability to produce these essential materials is highly desirable.

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Isotope sales are listed in the attached table titled "Isotope Production and Distribution Program" These numbers are for 1993 and are not yet final.

Also attached is a table that lists isotopes that DOE has ceased producing since 1980. For some, the demand has been satisfied by the private sector.

DRAFT

ISOTOPE.WU

ISOTOPE PRODUCTION & DISTRIBUTION PROGRAM
by Most Popular Isotopes

Isotope	Site	Revenues FY 1993	Revenues FY 1992	Revenues FY 1991	Revenues FY 1990
Yttirum 90	Argonne	$0.00	$10,483.32	$0.00	$0.00
Subtotal		$0.00	$10,483.32	$0.00	$0.00
Germanium 68	BNL	$100,376.00	$198,588.20	$143,921.00	$110,630.00
Strontium 82	BNL	$447,037.20	$309,413.60	$317,950.00	$163,576.00
Copper	BNL	$27,887.50			
Subtotal		$575,300.70	$508,001.80	$461,871.00	$294,206.00
Cobalt 60	Idaho	$117,431.41	$202,578.20	$38,500.00	$0.00
Iridium 192	Idaho	$821,651.25	$836,802.50	$666,907.00	$0.00
Nickel 63	Idaho	$0.00	$125,461.00	$171,000.00	$0.00
Subtotal		$939,082.66	$1,164,841.70	$876,407.00	$0.00
Aluminum 26	LANL	$36,844.29	$18,456.74	$22,432.00	$10,842.00
Americum 241	LANL	$49,910.00	$29,633.00	$0.00	$0.00
Cadmium 109	LANL	$167,550.00	$175,100.00	$120,816.00	$110,467.00
Copper 67	LANL	$29,922.00	$105,910.00		
Germanium 68	LANL	$405,863.00	$236,965.00	$164,962.00	$164,400.00
Sodium 22	LANL	$147,400.00	$82,348.00	$48,992.00	$48,830.00
Strontium 82	LANL	$390,950.00	$481,575.00	$632,575.00	$300,461.00
Subtotal		$1,258,439.29	$1,129,987.74	$989,777.00	$653,000.00
Deuterium	Mound	$14,412.64	$10,140.00	$6,845.00	$11,349.00
Helium 3	Mound	$283,340.63	$838,648.20	$1,373,058.00	$11,349.00
Krypton 78	Mound	$19,020.00	$3,426.50	$42,614.00	$466.00
Krypton 86	Mound	$0.00	$511.70	$78,232.00	$13,333.00
Nitrogen 15	Mound	$0.00	$12,542.86	$115,312.00	$328,065.00
Oxygen 18	Mound	$15,850.02	$24,276.00	$106,354.00	$173,293.00
Sulfur 34	Mound	$20,734.94			
Tritium	Mound	$473,702.59	$749,771.59	$1,409,525.00	$343,949.00
Xenon 124	Mound	$44,750.00	$0.00	$41,174.00	$6,122.00
Xenon 126	Mound	$0.00	$10,462.96	$26,696.00	$2,763.00
Xenon 129	Mound	$16,060.50	$0.00	$13,185.00	$5,310.50
Subtotal		$890,891.52	$1,649,761.81	$3,212,895.00	$897,999.50
Cadmium 112	ORNL	$84,000.00	$20,500.00	$43,600.00	$25,499.25
Calcium 42	ORNL	$330,000.20	$112,198.00	$79,216.00	$54,079.00
Calcium 44	ORNL	$48,031.60	$31,931.20	$104,954.00	$160,372.00
Calcium 46	ORNL	$23,379.90	$135,369.00	$50,261.00	$152,037.00
Calcium 48	ORNL	$85,031.55	$136,247.00	$48,936.00	$29,844.00
Californium 252	ORNL	$1,379,940.00	$1,488,285.00	$606,648.00	$1,156,777.00
Chromium 50	ORNL	$13,548.55	$69,345.95	$10,315.00	$1,718.00
Chromium 53	ORNL	$5,561.65	$14,161.75	$8,798.00	$5,891.00
Gallium 69	ORNL	$15,867.60	$11,700.00	$0.00	$997.00
Iridium 192	ORNL	$858,851.70	$0.00	$0.00	$0.00
Iron 54	ORNL	$0.00	$19,766.35	$17,577.00	$30,360.00
Iron 57	ORNL	$0.00	$0.00	$8,208.00	$1,095.00
Krypton 85	ORNL	$0.00	$182,760.00	$447,424.00	$330,324.00
Lead 204	ORNL	$6,729.00	$15,595.00	$3,112.00	$31,949.00
Lithium 6	ORNL	$20,930.00	$24,269.00	$73,575.00	$62,114.00
Lutetium 176	ORNL	$5,526.85	$63,854.20	$10,520.00	$1,290.00
Nickel 61	ORNL	$0.00	$30,115.00	$3,917.00	$2,553.00
Nickel 62	ORNL	$341,440.00	$223,701.00	$5,372.00	$11,434.00
Nickel 63	ORNL	$550,000.00	$0.00	$0.00	$0.00
Rubidium 87	ORNL	$108,960.70	$36,194.15	$92,198.00	$93,326.00
Samarium 152	ORNL	$0.00	$18,606.35	$10,390.00	$420.00
Silicon 29	ORNL	$0.00	$22,967.15	$43,057.00	$22,684.00
Strontium 84	ORNL	$4,641.00	$15,491.85	$54,685.00	$75,890.00
Strontium 88	ORNL	$674,902.51	$1,700,989.00	$439.00	$700,100.00
Tellurium 124	ORNL	$40,424.50	$74,584.00	$1,141.00	$72,862.00
Thallium 203	ORNL	$577,924.35	$338,959.50	$517,595.00	$2,616,748.00
Tritium	ORNL	$0.00	$0.00	$137,888.00	$1,328,248.98
Uranium 234	ORNL	$108,000.00	$235,000.00	$97,199.00	$258,200.00
Zinc 68	ORNL	$352,789.15	$71,903.75	$314,450.00	$670,294.00
Zinc 70	ORNL	$0.00	$15,014.25	$3,412.00	$36,732.00
Zirconium 96	ORNL	$0.00	$16,472.00	$12,695.00	$192.00
Subtotal		$5,636,320.81	$5,125,998.45	$2,807,504.00	$7,953,832.23
Cesium 137	WHC	$0.00	$537,000.00	$0.00	$0.00
Gadolinium 153	WHC	$0.00	$283,600.00	$945,300.00	$0.00
Yttirum 90	WHC	$167,970.00	$134,800.00	$54,352.00	$0.00
Subtotal		$167,970.00	$955,400.00	$999,652.00	$0.00
Total		$9,468,004.98	$10,544,494.82	$9,348,206.00	$9,799,039.73
Total Revenues		$14,010,657.00	$13,878,647.00	$11,525,832.00	$15,760,808.00
Percent		67.58%	75.98%	81.11%	62.17%

Isotopes that DOE has ceased producing since 1980. For some, the demand has been satisfied by the private sector.

Iodine-129
Promethium-147
Krypton-85 (both processed and enriched)
Xenon-127
Oxygen-17
Oxygen-18 (Intermittent availability)
Molybdenum-99
Iodine-131
Iodine-125
Xenon-133
Thorium-229
Plutonium-236
Phosphorus-32
Argon-36* (95 % enriched)
Argon-40* (99.95 % enriched)
Carbon-12* (99.9% enriched)
Carbon-13* (90-99% enriched)
Krypton-78* (8% enriched)
Krypton-78* (50-99% enriched)
Krypton-80* (70-90% enriched)
Krypton-82* (70-90% enriched)
Krypton-83* (70% enriched)
Krypton-84* (90% enriched)
Krypton-86* (50-99% enriched)
Neon-20* (99.95% enriched)
Neon-21*
Neon-22* (>70% enriched)
Xenon-124* (99% enriched)
Xenon-129* (80% enriched)
Xenon-134 (50% enriched)
Xenon-136* (60-99% enriched)

*DOE withdrew from production. Available from private sector.

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The Department conducted an internal, informal study of the potential for upgrading existing accelerator facilities at the laboratories and concluded that an upgrade to the Brookhaven Linac Isotope Producer (BLIP) facility would be the most economical and efficient way to achieve an enhanced radioisotope production capability. We completed a preliminary examination of the BLIP Upgrade as an interim solution to the shortage of large proton accelerator produced isotopes in the U.S. Results from this preliminary study indicated that the upgraded BLIP could supply a substantial fraction of the accelerator produced isotope needs in the U.S. Based on this preliminary examination, the Department felt that a more thorough review was required and charged the Institute of Medicine with examining the potential of the BLIP facility, as well as other facilities in the U.S., as an alternative to the NBTF.

Our examination of the BLIP capability included a review of the proposed BLIP upgrade with year-round operation, an extended year-round BLIP operating cycle without an upgrade, and the NBTF projected capabilities. We also included the scenarios with and without LAMPF operations. The attached BLIP Isotope Production Study provides the results of the review.

Also attached is a copy of the BLIP Construction Project Data Sheet as contained in the FY 1994 President's Request.

[The attached information is filed for the record in the Subcommittee office.]

STATEMENT

submitted to the

SUBCOMMITTEE ON

ENVIRONMENT, ENERGY AND NATURAL RESOURCES

HOUSE COMMITTEE ON GOVERNMENT OPERATIONS

UNITED STATES HOUSE OF REPRESENTATIVES

The Role of a dedicated U.S. Medical Isotope Production Reactor in Nuclear Medicine

December 6, 1993

Statement submitted by:

Russell M. Ball, Ph.D.

Senior Technical Consultant
Babcock & Wilcox - ASE
POB 10548
Lynchburg, Virginia 24506-0548
804/948-4728, fax 804/948-4803

The Babcock & Wilcox Company (B&W) appreciates this opportunity to present testimony relative to the United States production of short lived fission products used in nuclear medicine.

B&W has a long history (since 1867) of designing and constructing major installations for industry. After the discovery of nuclear fission and since the beginning of the use of nuclear processes for non-defense purposes, B&W has designed and constructed reactors for industry, utilities and educational institutions worldwide. The most recent nuclear facilities designed and constructed by B&W were an experimental reactor at Sandia National Laboratory (critical in October 1989) and a 3800 million watt power station in Germany (critical in March 1986).

Six reactor facilities, including a test and a research reactor, both of which produced radioisotopes, were licensed and operated at the Company's nuclear center in Lynchburg, Virginia. These reactors have been shut down but hot cell facilities remain in operation together with large scale development of nuclear fuel and fabrication of fuel assemblies and reactor cores..

In its role as a world class reactor designer, B&W has recently (1992) defined a dedicated fission reactor system, The Medical Isotope Production Reactor (MIPR), to produce medical isotopes and, in particular, molybdenum-99. B&W urges support of the initial 9-month phase of work on the MIPR with Federal development funds. This initial phase will increase confidence that in the second, two year, construction, licensing and commissioning phase, the MIPR can be completed at a reasonable cost and provide an assured U.S. supply of medical isotopes, employing U.S. labor.

MEDICINE AND ISOTOPES

Medicine and radiation have been partners in health for a century, beginning with the discovery of x-rays and continuing with the use of radioactive isotopes in diagnostics and therapy. In the United States, over 30,000 procedures each day rely on radioactive isotopes. Currently, molybdenum-99 (moly-99) and the daughter product, technetium-99m, account for 80% of nuclear medicine procedures. Pharmaceutical companies provide hospitals and clinics with systems which can "tag" biologicals with technetium-99m. These biologicals seek out particular organs which can be examined with gamma ray scanners.

The moly-99 has a short half-life (66 hours), so it must be produced in a reactor, shipped, and used within a two week period. Product preparation, packaging, and delivery to hospitals and patients are estimated to be an $8 billion/year business in the U.S., growing at over 10% per year. Since 1991, **no moly-99 is produced in the U.S.** All of this vital isotope is imported, principally from Canada. The Canadian production is based on the operation of a reactor (the NRU) started in 1957. The facility has had work stoppages in the past and there is no present backup.

MIPR HISTORY

The creation of moly-99 is now based on a "reactor-target" system; that is, a nuclear reactor is operated at high power to produce neutrons which then strike a target of fissionable uranium. After exposure, the target containing the fission products and the unfissioned uranium is dissolved, and the moly-99 is extracted by chemical separation and purified for shipment to pharmaceutical companies. Targets in the reactor produce about 100 kilowatts of heat. The reactor power to produce the irradiating neutrons produces about 10,000 kilowatts of heat. Thus, only 1% of the total fissions produced in the reactor and target is available as product. In the B&W Medical Isotope Production Reactor (MIPR), 100% of the product isotopes is available.

In 1944, as part of his work at the Los Alamos Laboratory, Richard Feynman designed a reactor (called a "water boiler") using a water solution of uranyl nitrate. The uranium was enriched to 14% U-235. The characteristics of the reactor were such that increases in power and temperature reduced the reactivity, and the operation was "self-limiting." The reactor type was considered to have the highest safety of any known reactor, and the water boiler was the first type of reactor built at a non-governmental site (N.C. State in Raleigh, North Carolina). Thirteen similar reactors were constructed and operated in later years.

In 1992, Babcock & Wilcox, combining the proven principles of the water boiler and modern improvements, developed the idea of the MIPR with the reactor solution in a container immersed in a large pool of water for passively safe heat removal. All of the fission products created by the nuclear fissions remain in the reactor solution and can be extracted on alumina ion-exchange columns. The attached figure shows the MIPR configuration.

ADVANTAGES

The MIPR would ensure safe, reliable production of the vital isotopes used in nuclear medicine. Currently, the U.S. is planning a limited capability to produce a backup supply but the effort has been troubled with costly environmental and technical difficulties. The MIPR's passive safety and infinite heat sink provide a unique, modern option to the Government for a stable level of isotope creation which is environmentally benign and cost-effective.

The MIPR advantages are:

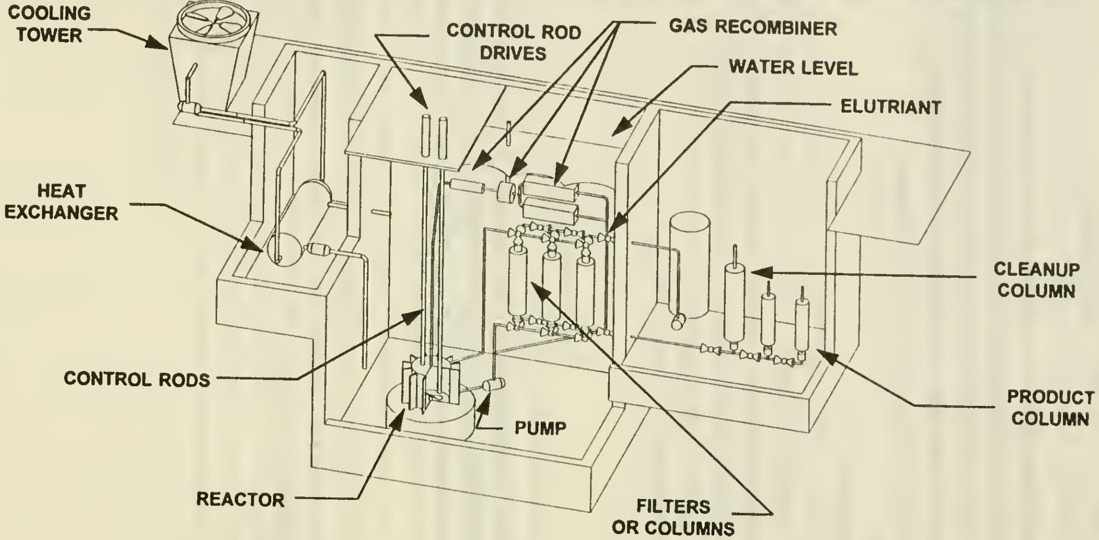
1. Passive safety and infinite heat sink
2. Waste products, waste heat, and uranium consumption are reduced by a factor of 100.
3. Dedicated production for nuclear medicine -- operation on demand
4. Lower cost to the health industry
5. Restoration of a U.S. business and jobs

THE PATH FORWARD

The concept has received critical reviews by technical personnel at national laboratories, radiopharmaceutical companies and universities. The MIPR has also been discussed with members of the staff of the U.S. Nuclear Regulatory Commission. The comments have all been positive and encouraging.

Construction of one or more MIPRs can lead the nuclear medicine community out of the dilemma of uncertain supply and rising costs. B&W looks forward to providing the technical support for early MIPR design and construction.

MIPR System Design



Babcock & Wilcox
a McDermott company
Advanced Systems Engineering

TESTIMONY OF
THE NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION

BEFORE THE

U. S. HOUSE OF REPRESENTATIVES
SUBCOMMITTEE ON ENVIRONMENT,
ENERGY AND NATURAL RESOURCES

COMMITTEE ON GOVERNMENT OPERATIONS

DECEMBER 6, 1993

NEMA, the National Electrical Manufacturers Association is pleased to provide testimony to the Subcommittee on Environment, Energy, and Natural Resources of the House Government Operations Committee.

NEMA is the nation's largest trade association representing America's electroindustries, with over 550 member companies. The association is comprised of nine separate divisions. One of those divisions, the Diagnostic Imaging and Therapy Systems Division, represents manufacturers of Nuclear Medicine Imaging devices, as well as computed tomography, x-ray imaging and therapy devices, diagnostic ultrasound devices, extracorporeal lithotripters, magnetic resonance devices and medical picture archiving and communication systems.

NEMA wishes to thank the subcommittee for affording us the opportunity to submit our testimony on the U.S. Department of Energy (DOE) Isotope Production and Distribution Program (IPDP). We applaud the subcommittee for holding these hearings in recognition of a critical national problem: the absence of an assured domestic supply of radioisotopes.

Since NEMA represents the overwhelming majority of the manufacturers of nuclear medicine imaging devices, the effectiveness of the Department of Energy Isotope Production and Distribution Program, and its impact upon the supply of isotopes to the nuclear medicine user community is a matter of profound concern to us. At present, there is no U.S. domestic source of supply of reactor-produced radioisotopes. Instead, users of these radioisotopes must rely on foreign sources, particularly, a reactor in Ontario, Canada which is operated by Nordion, Inc. Further, production of isotopes from accelerators at Los Alamos, Brookhaven and Argonne National Laboratories has nearly stopped. These accelerator-produced isotopes, such as Copper-67, Gallium -68, Strontium-82 and Cobalt-57, are crucial in treating cancer, in employing positron emission tomography, cardiac imaging and for calibration of nuclear imaging instruments, respectively. Finally, the supply of long-lived stable isotopes, used as targeting materials for various reactor-produced and accelerator-produced isotopes, will soon be depleted due to the near cessation of production and rapidly dwindling inventories.

We must not lose sight of the fact that the nuclear medicine industry is vital to the U.S. economy in terms of the number of jobs it represents, and its significance as a high technology growth industry of the future. Over 5,000 people are employed by the manufacturers of nuclear medicine equipment. The American Hospital Association has estimated that nearly 10,000 nuclear medicine technolgists were working in U.S. hospitals, along with more than 2,500 nuclear medicine physicians. Added to these numbers are approximately 5,000 employees who work on the production of radiopharmaceuticals.

Without an assured domestic supply of isotopes, many of these jobs will be imperiled. Correspondingly, innovation in nuclear medicine research, which lies at the heart of the future of this industry, will be placed in serious jeopardy.

Nuclear medicine in a vital part of the physician's arsenal in the diagnosis and treatment of disease. To illustrate its importance, it should be recognized that nearly one third of all hospital inpatients undergo some type of nuclear medicine procedure while in the hospital. Over 10,800,00 nuclear medicine procedures were estimated to have been performed in the U.S. alone in 1992. A shutdown of production of molybdenum - 99, which is used to produce one of the most widely used isotopes in nuclear medicine, technetium-99m, for even a very brief period would cause the cessation of most nuclear medicine diagnostic procedures performed in the U.S. within a few short weeks. This shutdown would have a disastrous effect on the life and health of millions of Americans.

The DOE program was begun in 1990. Its aims were to produce and sell isotopes for medical and other peaceful purposes. While the original funding of IPDP of $16,000,000 was intended, along with the proceeds of isotope sales, to make the program self-sustaining, in fact, expenditures have far outrun receipts. The DOE has been compelled to borrow $8,500,000 just to keep the program running. In the past few years, DOE has greatly reduced its presence in the market as a producer of isotopes, so that currently most users must rely on foreign sources for supply.

Saddled with aging isotope production facilities which are requiring increased funds for facility upkeep, and plagued by decreasing revenues from isotope sales, the DOE program is clearly in perilous financial condition. As a result, continuation of its existence as a reliable supplier has been seriously questioned. Another disturbing development is the trend that due to the uncertainty of the isotope supply in the U.S., many researchers are forsaking this country as a site for conducting advanced nuclear research, and turning instead to other nations where the issue of isotope supply is not an issue. As a consequence, the United States is threatened with the loss of its leadership position in the nuclear research field; this trend has ominous implications for the nation's economic future and the quality of health care in the U.S.

In its management study of IPDP, Arthur Andersen identified a number of problems with the IPDP, as currently operated by DOE. These problems included:

-Underpricing and wide variability in the price structure of isotopes, which has eroded customer support for the program, and greatly contributed to the lack of profitability in the sale of isotopes.

-Inaccurate allocation of production costs to IPDP isotopes, which has undermined financial control of the operation.

-Intermingling of research expenditures and production costs, thus creating confused and erroneous bookkeeping and diminished effectiveness of accounting systems.

Failure to follow "good business practices" in production, accounting and pricing decisions.

-Decentralized management of the isotope production program among the different laboratories producing isotopes, without a clear vision of the mission of the IPDP.

The Andersen report concluded that the IPDP should use an objective- based and profit- oriented personnel management system. Pricing should be done on a profitability basis, rather than tying prices to recovery of costs. A solid cost accounting system should also be implemented.

The critical situation presented by the current state of the DOE program underscores the urgent national need to draw upon both governmental and private support to assure the successful operation of the program and establishment of a reliable domestic source of supply for America's medical, technological and research requirements. NEMA believes that the creation of a National Biomedical Tracer Facility represents the best hope of addressing this crisis, and fulfilling our nation's need for isotopes. NEMA would like to share with the subcommittee our view as to how such a facility could help solve the isotope supply problem. The federal, state and local governments, industry and the scientific and academic communities can all play a constructive role in this regard.

Due to the substantial capital requirements which will be needed to plan, design and construct a National Biomedical Tracer Facility, a strong federal government commitment will be indispensable. Moreover, the achievement of the multiple goals of the facility, which include supply of isotopes for clinical practice, nuclear medicine research and scientific applications, are and will be essential to the viability of our nation's industrial base and the health and well-being of America's citizens. It is thus clearly in the national interest for the federal government to become committed to providing strong support for this effort.

NEMA, along with the American College of Nuclear Physicians, Society of Nuclear Medicine, and other industrial and scientific groups, has proposed to the House Appropriations Committee, Subcommittee on Energy and Water Development, that $25,000,000 be appropriated for FY 94, with $100,000,000 to be allocated over the next four years, for siting, development and construction of the National Biomedical Tracer Facility. Once this "seed money" has been appropriated, the federal government could then contract with a private firm or consortium of firms for the operation, management and maintenance of the facility.

Industry should have a vital responsibility in the support of this facility. NEMA proposes that a consortium of companies, join together to contribute capital for the facility. Industry can also make other invaluable contributions to enable such a facility to succeed. U.S. manufacturers of nuclear imaging equipment have a solid base of know-how and experience in private sector management. Specifically, industry could put into place cost accounting systems, financial controls, and management-by-objective systems. With the implementation of these practices and establishment of pricing structures based on profitability, these measures would go a long way towards fashioning a remedy for the problems set forth in the Arthur Andersen report, and for keeping the program on track. Support could also be generated from industry involvement by the sales of isotopes, corporate funding of specific research, and by staffing the facility with the necessary managerial, administrative and technical people.

NEMA believes that a "Joint Management Committee" should be established to provide operational responsibility for the program. This group would be comprised of representatives from government, the academic and scientific communities, and industry. Hence, this body would reflect the multiplicity of purposes for

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which the biomedical tracer facility was established. A U.S. Department of Energy, Office of Inspector General report in 1988 criticized the DOE program for its lack of overall centralized management of the various producing facilities under its jurisdiction. The Joint Management Committee could correct this problem by acting as the chief executive body for the facility, and serving as a single point of accountability and decision-making, and by developing a coherent, consistent strategic direction for the biomedical tracer facility. Furthermore, the facility could eventually be put on a profitable basis by instituting the sound management practices outlined above.

In addition to the participation from industry, the facility should have, as part of its governing structure, representatives from the scientific and academic communities. These personnel would be necessary to conduct the teaching and research activities of the facility. With the inclusion of these diverse interests on the Joint Management Committee, many ingenious mechanisms could be developed in terms of joint research and development projects to advance scientific knowledge in nuclear physics, and a host of related fields. The potential would also exist for enlisting the financial support of the institution on which the facility was sited, and from affected parts of the scientific community.

In conclusion, NEMA wishes to recognize the valuable service that the Arthur Andersen report has performed, by identifying the major problems involved in the current operation of the IPDP. We believe that this report has taken the first necessary step to developing a means to address these problems.

NEMA urges that the necessary measures be taken to change the DOE program by adopting a public-private "partnership" model as outlined in our testimony. We have a unique opportunity to create a facility which can provide not only a reliable supply of isotopes, but also assure the continued strength and leadership of nuclear medicine research in the U.S. This will enhance the health and well-being of the American people. The future economic base of this country and welfare of its citizens demand no less. NEMA stands ready to work with the Congress and other interested parties to make the establishment of a domestic biomedical facility an important national objective.

QUESTIONS FROM REPRESENTATIVE SYNAR

Isotope Program Funding

Question 1(a): In your oral testimony, you committed to capital expenditures to support the isotope program, including capital expenditures required for Omega West. You also stated that there would be a reprogramming for such support and that the department would budget funds in FY 1995 for this purpose. Please describe the capital investment program for the isotope program including specific facilities and amounts of funds to be invested.

Answer: The Department has completed a reevaluation of DOE and university reactors with a capability to produce molybdenum-99. Two small research reactors are candidates, the Annular Core Research Reactor at Sandia National Laboratories and the Omega West Reactor at the Los Alamos National Laboratory, in addition to the Advanced Test Reactor in Idaho. The Office of Nuclear Energy and the Office of the Chief Financial Officer are in the process of identifying FY 1994 funds to continue this initiative. A selection will be made this spring.

The FY 1995 budget request includes $3.3 million for the molybdenum-99 initiative. Fiscal Year 1994 funds of approximately $2-4 million are estimated to be needed for the molybdenum-99 initiative depending on the date of initiation of the work. No other capital investments are planned for the Isotope Program in FY 1994 or FY 1995.

However, other Departmental programs are making capital expenditures which will provide the capability and capacity to produce isotopes.

In FY 1994, $6 million was provided by Congress to the Office of Energy Research for upgrading the Brookhaven Linear Isotope Producer. This upgrade is scheduled for completion in June 1996.

QUESTIONS FROM REPRESENTATIVE SYNAR

Isotope Program Funding

Question 1(b):	Identify what funds will be reprogrammed and the expenditures that will be made to support the isotope program; please provide the specific FY'94 reprogramming request.
Answer:	The Office of the Chief Financial Officer and the Office of Nuclear Energy are currently working together to identify funds for the Isotope Program to provide for working capital and continuity of the Isotope Program, and continuation of the molybdenum-99 and other related medical isotopes initiative. Specifics for this funding request will be provided to you when completed.

QUESTIONS FROM REPRESENTATIVE SYNAR

Isotope Program Funding

Question 1(c): The testimony also stated that funds would be requested in the President's FY'95 budget to support the isotope programs and the FY'95 budget includes $7.3 million for this purpose. Provide a detailed activity-by-activity description of the overall FY'95 budget for the isotope production and distribution program.

Answer: The $7.3 million included in the fiscal year 1995 budget includes $4.0 million to support program operations and $3.3 million for the molybdenum-99 project. The detailed activity-by-activity description of the overall fiscal year 1995 budget for the Isotope Production and Distribution Program will be available soon when the Department submits to Congress a National Isotope Strategy and associated funding requirements.

QUESTIONS FROM REPRESENTATIVE SYNAR

Omega West

Question 2(a): At the hearing, you announced that the Department was going to proceed with the Omega West isotope production mission. We now understand that the Department is considering an alternative reactor to produce medical isotopes. Describe why the Omega West decision announced at the hearing is being reconsidered, the actions the Department is taking to proceed with this mission, and provide the detailed work plans, budgets, and schedules implementing this mission.

Answer: Three reactors, Omega West at Los Alamos National Laboratory, the Annular Core Research Reactor at Sandia National Laboratories, and the Advanced Test Reactor at the Idaho National Engineering Laboratory are being considered for production of molybdenum-99 and related isotopes. The Omega West Reactor has been found to need extensive repair and modernization. The Advanced Test Reactor would need substantial modifications to prepare it for production of molybdenum-99 and related isotopes. Its operating cycle also precludes continuous production of these isotopes. A backup supply of isotopes would be needed for those times that the Advanced Test Reactor is not available.

The Annular Core Research Reactor, a small test reactor located at Sandia, has been determined to be suitable for the medical isotope mission. The Sandia reactor is operational and has been maintained and upgraded to current Department standards. The overall costs and schedule to place the Sandia facilities in production are less than at Omega West. The operational production costs are also less at Sandia.

The Sandia reactor is a Defense Programs facility. Defense Programs is evaluating their future needs for this facility to determine if it can be made available for the medical isotope mission.

Detailed work plans, budgets, and schedules will not be developed until a final decision is made.

QUESTIONS FROM REPRESENTATIVE SYNAR

Omega West

Question 2(b):	Omega West has been a Defense Programs facility. Describe which program office will be responsible for managing Omega West and the procedure and the schedule for transferring this facility to another office if it is to occur.
Answer:	Two of the three reactors under consideration, Omega West and the Annular Core Research Reactor, are currently the responsibility of Defense Programs. As part of the decision as to which reactor is to be used for molybdenum-99 production, a decision as to whether or not to change program office responsibility will be made. We will inform you of this decision and provide the procedure and schedule for facility transfer, if required, within 90 days of this decision.

QUESTIONS FROM REPRESENTATIVE SYNAR

Omega West

Question 2(c): Beginning immediately, the Department committed to correcting safety deficiencies at the Omega West Reactor prior to restart along with repair of the cooling leak. While we realize that the actual decision to use Omega West is being reevaluated, please identify, for each reactor under consideration for the medical isotope mission, all existing safety deficiencies that need to be corrected, estimated cost and timetable for these corrections, the timetable for initiating isotope irradiation, and the actions that have been taken to date in this regard.

Answer: Annular Core Research Reactor at Sandia National Laboratories

There are no identified safety deficiencies at the Sandia Reactor. The hot cell facilities at Sandia will require substantial work and time to be made ready for production. Hot cell work involves cleaning and decontaminating the hot cells, then installing internal shield walls. The hot cell facility building will require new access points and some other internal rearrangement. After preparation of the hot cells, the installation and testing of the isotope processing system will require a few months. Overall it is expected that up to 18 months will be required to prepare the hot cells and processing equipment for production. The overall costs for the conversion of the Annular Core Research Reactor and hot cells for molybdenum-99 production include non-safety modifications that are required for reliable isotope production. Two years are required from project start until qualified isotopes are available for sale. The overall estimated cost for the project is $11.4 million.

Omega West and Los Alamos Hot Cell Facilities

There are two identified deficiencies at Omega West. These include the earlier coolant leak and the safety of overall conduct of operations. There are a number of safety issues that would require further evaluation to determine their significance and applicability to Omega West. These include seismic hazard assessments and the effects of flooding and storage of spent fuel.

The Office of Nuclear Energy estimates that $14 to $15 million would be required to prepare the Los Alamos facilities for medical isotope production. This estimate is preliminary because engineering solutions to the identified issues are not yet fully developed. Considering the overall set of activities that would have to be completed and the need to address a large number of issues that would be likely to be raised as part of the restart process, Nuclear Energy believes that it would require at least three years to have these facilities ready for production.

Advanced Test Reactor and Hot Cell Facilities

There are no known safety issues that apply to the Advanced Test Reactor and hot cell facilities. Production of molybdenum-99 and related isotopes would require the installation of a new mechanism to insert targets into the reactor while it is operating. Target preparation and processing equipment would need to be installed in existing hot cells. Because the operating cycle of the Advanced Test Reactor does not allow continuous operation throughout the year, a second reactor would be required to produce molybdenum-99 during the 50 to 70 days when the Advanced Test Reactor is unavailable.

The Idaho National Engineering Laboratory has estimated production preparation costs for the Advanced Test Reactor and processing facilities at $12 to $20 million plus the cost of a new reactor, approximately $25 million. The modified Advanced Test Reactor could be available for production in approximately two years. The new reactor could be available in five years.

QUESTIONS FROM REPRESENTATIVE SYNAR

Omega West

Question 2(d): At the time of the hearing the environmental assessment supporting the Omega West isotope production mission was under review by DOE's Office of Environment, Safety and Health. Describe the current status of this NEPA action, identify any issues raised by ES&H in its review and how they are being addressed, and provide the current draft and final drafts of this environmental assessment.

Answer: Since the Department has placed the proposal to operate the Omega West Reactor for production of medical isotopes on hold pending evaluation of another reactor, the environmental assessment has not been completed. Among the concerns raised by the Office of Environment, Safety and Health regarding the Omega West Reactor were the age of the reactor, coolant leak, plans for spent fuel management, seismic issues, and the status of safety documentation. The Office of Nuclear Energy currently is considering options for the production of medical isotopes and will prepare the appropriate National Environmental Policy Act documentation prior to a decision on whether and how to proceed. The draft environmental assessment for Omega West is enclosed, as requested.

[The information is filed for the record in the office of the Subcommittee.]

QUESTIONS FROM REPRESENTATIVE SYNAR

Restructuring of Isotope Program

Question 1(a): Your testimony states that the Department intended to adopt many of the Arthur Andersen and Company recommendations and you committed to provide an item-by-item response on which of those recommendations would be adopted. Identify the Arthur Andersen recommendations that have been, or will be adopted, and provide the Department's schedule for their implementation.

Answer: The Arthur Andersen and Company report provides recommendations for placing the Isotope Production and Distribution Program on an efficient and sustainable basis consistent with Public Law 101-101 full-cost recovery requirements. The report recognizes, however, that operation of the Isotope Program, consistent with the full-cost recovery concept, would require the Department to give special accounting and management treatment to the Isotope Program that is unprecedented in the Department, treatment that the report also recognizes would be very difficult to achieve.

In response to a congressional request, the Department will very shortly submit to Congress a National Isotope Strategy that will address the Arthur Andersen recommendations and will, with your help, establish the Department's own goals and procedures for maintaining a long-term financially viable isotope enterprise that will go far toward meeting the expanding needs of domestic research and development, industry and medicine. The strategy will include the Department's views on the legislation needed to address and alleviate the current difficulties of the program which have resulted from the full-cost recovery requirements of Public Law 101-302.

QUESTIONS FROM REPRESENTATIVE SYNAR

Restructuring of Isotope Program

Question 3(b): At the hearing, you acknowledge that the revolving fund had been unsuccessful in supporting the isotope program, and you indicated that the Department would prepare legislation to modify the existing statutory requirements of P.L. 101-101 related to the fund. Provide the Department's schedule for preparing this legislation and identify the individuals and offices responsible for completing this task.

Answer: The revolving fund has been unsuccessful in supporting the Isotope Program. As indicated in our response to the previous questions, the Department has developed views on what will be required to correct, legislatively, the adverse impact that Public Law 101-101 has had upon the Isotope Program. We are preparing legislation to modify the existing statutory requirements of Public Law 101-101 that is related to the fund, and this will be submitted to Congress shortly. This legislation is being prepared by the Office of Nuclear Energy, the Office of the Chief Financial Officer, and the Office of the General Counsel.

QUESTIONS FROM REPRESENTATIVE SYNAR

Restructuring of Isotope Program

Questiun 3(c): You stated the Department needed to assemble a body of outside experts to advise the Department on restructuring the isotope program. Provide the Department's schedule for establishing this panel, its charter, and milestones for providing advice the Department.

Answer: The Department will submit to Congress shortly a strategic plan that addresses the involvement of outside experts among the Department's customers and stakeholders to provide advice on the structure and operation of the Isotope Program.

QUESTIONS FROM REPRESENTATIVE SYNAR

Restructuring of Isotope Program

Question 3(d): You testified the Department intended to explore alternative marketing approaches, such as commissioned sales agents. Describe the Department's plan to examine and implement schedule for implementing such approaches.

Answer: The Department will explore effective marketing strategies for isotope products and services. The Headquarters position of marketing manager will be filled with a Federal employee as soon as possible. In the interim, an experienced marketing professional at one of the production sites is developing marketing initiatives at the direction and subject to the approval of the Isotope Program Director.

Marketing will interact with customers to assure that their concerns receive immediate attention and that isotope products meet quality and schedule expectations. Marketing will seek to expand sales and identify new business opportunities by maintaining current knowledge of world markets.

The Department will seek to identify private sector experts who can assist the marketing effort and will use them as appropriate in characterizing domestic and international isotope markets and developing product and pricing strategies. A comprehensive marketing plan will be developed by September 30, 1994.

QUESTIONS FROM REPRESENTATIVE SYNAR

Restructuring of Isotope Program

Question 3(e): In the context of the Subcommittee's discussion of the Advanced Neutron Source and the Department's capability to meet future isotope production requirements, you stated that the Department knew what future isotope requirements would be and that this information would be provided to the Subcommittee. Provide this information.

Answer: The Department has confidence that the short-term future isotope demand (fiscal years 1994 and 1995) will not deviate significantly from demand in fiscal year 1993. A listing of prominent isotopes sold in fiscal year 1993 is attached. However, continuing aggressive pricing by the New Independent States of the former Soviet Union of stable and longer half-life radioisotopes may impact the Department of Energy's market share. Longer term production requirements are more difficult to predict. The Department expects that continuing interaction with its customers and the development of a comprehensive marketing plan, scheduled for completion on September 30, 1994, will define the production requirements for isotopes.

Enclosed is a list of isotopes produced and sold by location in fiscal year 1993 by the Isotope Production and Distribution Program.

ISOTOPES PRODUCED AND SOLD BY LOCATION
IN FISCAL YEAR 1993

Isotope	Units Produced	Value
Brookhaven National Laboratory		
Copper-67	398 mCi	$ 27,887
Germanium-68	398 mCi	100,376
Strontium-82	4,539 mCi	612,037
Other Isotopes		11,389
Total		$ 751,689
Idaho National Engineering Laboratory		
Cobalt-60	4,561 mCi	2,328
Iridium-192	389,616 mCi	821,651
Total		$ 823,979
EG&G Mound Applied Technologies		
Deuterium	57,661.37 L	$ 14,412
Helium-3	3,634.60 L	283,340
Krypton-78	1.00 L	19,020
Nitrogen-15	24.00 g	4,240
Oxygen-18	155.50 g	15,850
Sulfur-34	30.90 g	20,734
Tritium	140,158.39 cI	473,702
Xenon-124	1.30 L	44,750
Xenon-129	6.50	19,080
Other Isotopes		189,470
Total		$1,084,598
Los Alamos National Laboratory		
Aluminum-26	.0993 microCi	$ 36,844
Americum-241	67.00 g	49,910
Cadmium-109	3,564.00 mCi	197,550
Copper-67	408.00 mCi	29,922
Germanium-68	1,553.50 mCi	405,863
Sodium-22	1,701.50 mCi	147,400
Strontium-82	4,255.00 mCi	390,950
Other Isotopes		111,952
Total		$1,370,391

Metric Symbols

Ci = Curie
g = gram
mCi = millicurie
mg = milligram
L = liter

Oak Ridge National Laboratory

Isotope	Units Produced	Value
Cadmium-112	20,000 mg	$ 84,000
Calcium-42	311 mg	24,567
Calcium-44	20,000 mg	37,173
Calcium-46	6 mg	23,379
Calcium-48	272 mg	59,718
Californium-252	28,720 mg	1,379,940
Chromium-50	203 mg	13,548
Chromium-53	197 mg	5,581
Copper-65	1,638 mg	7,944
Dysprosium-163	20 mg	80
Iridium-192	369,242.40 Ci	858,651
Iron-54	6,284.00 mg	6,453
Iron-57	3,658.00 mg	10,055
Lead-204	60.00 mg	6,729
Lithium-6	16,744.00 g	20,930
Lutetium-176	27.00 mg	5,526
Nickel-61	56.00 mg	2,950
Nickel-62	22,115.00 mg	163,940
Nickel-63	160,000.00 mCi	550,000
Rubidium-87	10,186.00 mg	108,980
Samarium-15	760.00 mg	1,672
Silicon-29	24.00 mg	1,644
Strontium-84	26.00 mg	4,641
Strontium-88	758,259.00 mg	674,902
Tellurium-124	1,520.00 mg	40,424
Thallium-203	195,021.00 mg	577,924
Uranium-234	2,000.00 mg	108,000
Zinc-68	53,051.00 mg	352,789
Zinc-70	10.00 mg	3,316
Other Isotopes		896,471
Isotope Services (e.g., conversion)		$1,270,717
Total		$7,302,644

Westinghouse Hanford Company
Pacific Northwest Laboratory

Yttrium	$ 167,970
Cadmium-109	5,730
Total	$ 173,700

Metric Symbols

Ci = Curie
g = gram
mCi = millicurie
mg = milligram
L = liter

QUESTIONS FROM REPRESENTATIVE SYNAR

Restructuring of Isotope Program

Question 3(f): The Arthur Andersen report found that direct and indirect overhead charges and costs of production facilities threatened the economic viability of the Department's commercial isotope production activities. Identify the action the Department is taking to control these charges and costs as they relate to the isotope program.

Answer: Control of costs is a major challenge for the Isotope Production and Distribution Program since many costs are driven by factors beyond the direct control of the Isotope Program control. Most facilities that provide isotopes exist to support other, much larger Government programs. To control costs, the Arthur Andersen report recommended that only the incremental overhead costs of production be allocated from the laboratories to the Isotope Program. This arrangement would require deviation from the Department's full-cost recovery policy used for other programs. It would result in providing unique treatment of the Isotope Program among all Department of Energy programs. We have decided to implement this recommendation consistent with our generic policy.

The Department has undertaken, or will undertake, four initiatives that, when fully implemented, will improve cost control and ensure that costs attributable to the production, processing, and distribution of isotopes are accurately charged to the Isotope Program.

First, in 1993, the Isotope Program requested through the Office of the Chief Financial Officer that the isotope production sites conduct a self-assessment of indirect costs. The self-assessment resulted in a better understanding of indirect costs at each site and identified several issues that we are attempting to resolve in future negotiations with the production facility operators. For example, at some sites, costs for some facilities or activities that provide no benefit to isotope production are allocated by formula to all activities at the site. The Isotope Program will attempt to negotiate a change in the formula that reduces the Isotope Program's share of such costs. By resolving these issues, the Department will be able to better control production costs.

Second, the Department's response to recommendations by KPMG Peat Marwick, certified independent auditors, provided as a result of their financial audit of the Isotope Program's financial statements for fiscal years 1992 and 1993, will also improve cost controls. For example, a detailed product/project cost system will be fully implemented in fiscal year 1996.

Third, the Isotope Program will maintain close contact with managers of facilities and programs that have potential impact on isotope production and availability to assure that the Isotope Program is a party in decisions that potentially affect the production and distribution of isotope products and services. For example, changing conditions that may impact the allocation of costs among users of shared facilities will be known to the Isotope Program before decisions are made. Thus, the Isotope Program will have the opportunity to negotiate equitable allocation of such costs.

Fourth, the Isotope Program is also beginning discussions with the operators of the production facilities. These understandings, which will complement any actions taken within the provisions of the existing management and operating contracts, will aid in achieving greater cost and pricing predictability.

QUESTIONS FROM REPRESENTATIVE SYNAR

Restructuring of Isotope Program

Question 3(g): The Department has a number of "non-commercial" isotope production requirements for tritium to maintain weapons stockpiles, plutonium-238 to support space program missions, research programs pursued by the Office of Energy Research for both medical and transuranic isotopes. Similarly, production facilities used for "commercial" isotope production are controlled and funded by other Department programs such as physics programs. Describe how the Department intends to integrate planning and operational activities associated with "commercial" isotope production with its internal isotope production facility operations and programs such as the Advanced Neutron Source.

Answer: The Isotope Production and Distribution Program maintains an awareness of isotope production capabilities and isotope stockpiles throughout the Department of Energy complex, where isotopes produced for internal purposes have potential for sale outside of the Department. The Isotope Program seeks agreements with the Department elements that produce or stockpile such isotopes to make them available to meet its needs. For example, a small quantity of tritium, an isotope that is primarily used for weapons, has been reserved for sale through the Isotope Program because a commercial need for it has been identified by customers. No current market demand for plutonium-238 has been identified. However, operation of existing facilities that have primary missions other than isotope production has been successfully coordinated with the Isotope Program's need to make certain isotopes available for sale. For example, Isotope Program representatives at the Idaho National Engineering Laboratory coordinate the use of the Advanced Test Reactor to irradiate targets that produce iridium-192 and cobalt-60 for industrial applications.

For planned facilities such as the Advanced Neutron Source, an overall research and production plan will be developed which will integrate the research and production missions.

The Isotope Program, through outreach to its customers and stakeholders, including researchers sponsored by other organizations within the Department, will continue to define and clarify future isotope production needs and to coordinate production operations. These outreach activities are described in the National Isotope Strategy that will soon be available to Congress.

QUESTIONS FROM REPRESENTATIVE SYNAR

Fast Flux Test Facility Shutdown Decision

Question 4(a): On the day of the hearing, the Department announced that it would shut down the Fast Flux Test Facility. The letter announcing this decision referred to the findings of the independent review team as the basis for this decision. As discussed in the hearing, the independent review team (the "Landis Committee") specifically stated that its recommendation to shut down the facility was predicated on the Department's review of the isotope production mission, which obviously did not occur. Provide a description of the process used by the Department in making its determination to shut down the Fast Flux Test Facility and all supporting documentation.

Answer: In a December 6, 1993, letter, Secretary O'Leary notified Congress of the Department's decision to permanently shut down the Fast Flux Test Facility. The basis for this decision was the findings of the Independent Review Team (i.e., the Landis Committee) commissioned by the Department to evaluate a multimission role for the facility and the results from internal reviews of the capabilities of the Department's remaining facilities.

The findings of the Independent Review Team were documented in the report, "Future Use of the United States Department of Energy's Fast Flux Test Facility," dated September 20, 1993. The Independent Review Team's primary conclusion was that there was no combination of compatible missions for the Fast Flux Test Facility that had a reasonable probability of making the facility financially viable over the next ten years. The Independent Review Team recommended that the facility be shut down provided the Department was satisfied that the remaining facilities have the capability to carry out the various missions they will be asked to perform, including the mission of supplying medical isotopes.

An internal review of the capabilities of the Department's remaining facilities was conducted and the results documented in the report, "The Long-Range Plan for Utilization, Retirement, and Replacement of the Department of Energy Nondefense Test and Research Reactors," dated November 22, 1993. The long-range plan concluded that the missions essential to the discharge of the Department's current responsibilities are being fulfilled by the test and research reactor complex. The plan further concluded that significant mission flexibility and capacity exists within the complex to enable the Department to meet projected and potential future needs.

The Fast Flux Test Facility has historically provided only a very small part of the Department's radioisotope production capacity. In developing the long-range plan, the Department reviewed the Nation's radioisotope research and production capabilities and concluded that there were no radioisotopes which could only be produced in the Fast Flux Test Facility and that the existing Government and private sector reactors could meet projected market needs for reactor-produced radioisotopes.

The United States currently relies on Canada for its supply of molybdenum-99. A continued and reliable supply of this radioisotope is critical, as it is used in more than 30,000 medical procedures daily in the United States. In view of this situation, the Department's Isotope Production and Distribution Program has initiated an effort to develop a domestic supply capability for these radioisotopes. As part of this effort, the Fast Flux Test Facility was evaluated for production potential and was determined not to be a viable option based on cost and operational considerations. A small reactor that can be fully dedicated to the production of molybdenum-99 is preferred. The Omega-West reactor at Los Alamos and the Annular Core Research Reactor at Sandia are currently being evaluated for production of molybdenum-99.

Copies of the reports "Future Use of the United States Department of Energy's Fast Flux Test Facility" and "The Long-Range Plan for Utilization, Retirement, and Replacement of the Department of Energy Nondefense Test and Research Reactors" are attached.

[The attachments are filed for the record in the office of the Subcommittee.]

QUESTIONS FROM REPRESENTATIVE SYNAR

Research Reactor Status

Question 4(b): Provide a description of the process used to establish the charter and mission for the independent review team (the "Landis Committee") and all supporting documentation.

Answer: In a May 6, 1993, letter to Secretary O'Leary, the Washington State Congressional Delegation requested the Secretary to "commission an independent analysis to explore a multimission role for FFTF within the context of your agency's long-term goals." The analysis by the independent review team, known as the "Landis Committee," was carried out to comply with this request. The work requirements were developed by the Office of Nuclear Energy in consultation with the Office of the Secretary and by letter dated June 15, 1993, the Secretary notified the Washington State Delegation and other members of Congress that the Department was arranging for the conduct of an independent study to explore a multimission role for the FFTF. The independent review team effort was carried out by subcontract under the Department's contract with Halliburton NUS Corporation. The statement of work directing the analysis was incorporated into the subcontract between Halliburton NUS Corporation and

John Landis, which was executed on June 1, 1993. Copies of the congressional correspondence and the Halliburton NUS Corporation-John Landis agreement are attached.

[The attachments are filed for the record in the office of the Subcommittee.]

QUESTIONS FROM REPRESENTATIVE SYNAR

Research Reactor Status

Question 4(c): Pursuant to recommendations made by the General Accounting Office in a report prepared at the request of this Subcommittee, the Department produced a long-range plan on the utilization of its research reactors. As discussed the hearing, this report did not incorporate the findings of the Department's strategic planning process nor did it provide a comprehensive analysis of the Department's research reactor requirements and capabilities. Provide the results of the Department's strategic planning process, begun in August 1993, which you discussed in your testimony.

Answer: The Long-Range Plan for the Utilization, Retirement, and Replacement of Department of Energy (DOE) Nondefense Test and Research Reactors addressed the Department's current and projected mission requirements and assessed the capabilities of the existing test and research reactors to meet those requirements. The plan was approved by the Office of Nuclear Energy on November 12, 1993, and by the Office of Energy Research on November 22, 1993.

The results of the Department's overall strategic planning efforts are presented in the Department's strategic plan released on April 5. A copy is attached. The strategic plan identifies the "Business Strategies" of the Department and the factors that will be utilized to measure success towards achieving the Department's goals. The long range plan is consistent with and supports the Department's strategic plan.

[The report entitled Fueling A Competitive Economy: Strategic Plan is filed for the record in the office of the Subcommittee.]

QUESTIONS FROM REPRESENTATIVE SYNAR

Research Reactor Status

Question 4(d): The long-range plan for research reactors was not reviewed by DOE's Office of Environment, Safety and Health, but you committed to determine how that office could be involved in long-term strategic planning decisions. Explain why the long-range plan on research reactors was not transmitted to the Office of Environment, Safety and Health for review and describe what procedures are in place to ensure that office will be involved in any revision of this plan and in such actions in the future.

Answer: The review of the Office of Environment, Safety and Health in the long-range plan for test and research reactors was not requested nor was it considered appropriate for this document. The long-range plan is a programmatic document developed to assess the capabilities of the Department's test and research reactors to meet current and projected mission requirements. The plan provided replacement schedules for existing reactors where appropriate and a general description of the programs in place to ensure the safety of the reactors as they age.

The Office of Environmental, Safety and Health provides ongoing safety oversight of the Department's reactors. In fulfilling this responsibility, the Office of Environment, Safety and Health has full access to all of the technical documentation that provides the bases for their continued safe operation including the documents that define the plant aging and inspection programs that are cited in the long-range plan. Further, the Office of Environment, Safety, and Health performs safety reviews of reactors undergoing major changes such as a major change in mission or a major change to the safety basis. Consequently, specific review by the Office of Environment, Safety and Health of any future revision to the long-range plan is not considered essential.

QUESTIONS FROM REPRESENTATIVE SYNAR

Research Reactor Status

Question 4(e): Describe what steps the Department is taking to remedy the deficiencies in the long-range plan for research reactors signed by Dr. Krebs and Dr. Dreyfus on November 22, 1993, and November 12, 1993, respectively.

Answer: The Department proposed to Congress in the FY 1995 Budget Request that the Integral Fast Reactor and the Actinide Recycle Programs be terminated beginning in FY 1995. If approved, operations of the Experimental Breeder Reactor-II will be terminated at the beginning of FY 1995 rather than at the end of FY 1996 as currently stated in the long-range plan for nondefense research and test reactors. The Department is also considering utilizing a Defense Programs research reactor for molybdenum-99 production. A decision is expected in the near future, and the long-range plan will be updated and National Environmental Policy Act review would be conducted as appropriate.

QUESTIONS FROM REPRESENTATIVE SYNAR

Research Reactors Status

Question 4(f):	Explain why Dr. Dreyfus informed the Subcommittee on November 23, 1993, that the long-range plan for research reactors had not been completed and could not be provided to the Subcommittee at that time when, in fact, both Dr. Dreyfus and Dr. Krebs had already signed the report.
Answer:	Mr. Dreyfus' letter to Mr. David Berick dated November 23, 1993, indicated that the long-range plan had not been completed because the Office of Nuclear Energy had not received Dr. Kreb's approval of the plan. In fact, it was later learned that she had signed the plan on November 22, 1993, the previous day. The approved plan was provided to Mr. Berick on November 29, 1993.

QUESTIONS FROM REPRESENTATIVE SYNAR

Research Reactor Status

Question 4(g): Prior to the hearing, the Subcommittee requested an analysis of the isotope production capability of the Advanced Neutron Source for non-transuranic isotopes. The Subcommittee was informed by Dr. Dreyfus on November 23, 1993, that this information could not be provided, even though we were informed by personnel at Oak Ridge National Laboratory that such information could be provided. In your testimony, you committed to provide this information. Please provide the information originally requested.

Answer: In my testimony, I committed to provide you with information that is readily accessible regarding the Advanced Neutron Source isotope production capability. The Oak Ridge National Laboratory report, ORNL/TM-12010, "Production Capabilities in U.S. Nuclear Reactors for Medical Radioisotopes" is currently being updated with a supplement to include calculations on production capabilities of the Advanced Neutron Source for key medical radioisotopes, specifically copper-67, tin-117, holmium-166, platinum-195, rhenium-188, and molybdenum-99. These medical isotopes were selected based on current interest and importance. We will provide the information currently being developed by the Oak Ridge National Laboratory by May 1, 1994.

QUESTION FROM REPRESENTATIVE SYNAR

Research Reactor Status

Question 4(h): Provide the results of the Department's review of changing the fuel for the Advanced Neutron Source to a lower enrichment level, along with all supporting documentation, and describe any changes that will be made in the design as a result of this review, the cost of such changes, if any, and the effect on schedule.

Answer: The conceptual design of the Advanced Neutron Source is based on the use of a highly enriched uranium fueled core. The Department, in the FY 1994 Congressional Budget Request, committed to undertake a study to examine the impact on the Advanced Neutron Source performance goals if low or medium enriched uranium fuel is used. A draft report, dated January 31, 1994, documents the results of a study conducted by the Brookhaven National Laboratory with participation from Argonne National Laboratory, Idaho National Engineering Laboratory, and Oak Ridge National Laboratory. A copy of the draft report is attached. The results of a review of the Advanced Neutron Source fuel performance are also provided for your information.

The Department is currently evaluating the results of these reviews for the feasibility of using low or medium enriched uranium fuel for the Advanced Neutron Source. The evaluation is addressing the impact of using low or medium enriched fuel on the performance, safety, cost, and schedule.

[The attachment is filed for the record in the office of the Subcommittee.]

QUESTIONS FROM REPRESENTATIVE SYNAR

Research Reactor Status

Question 4(i): Describe the current status of the Advanced Neutron Source project including the status of the Department's decision on the regulatory regime that will be applied to this facility. Also describe the process and provide criteria to be used by the Department to determine which regulatory regime will be applied.

Answer: The Advanced Neutron Source is currently in the advanced conceptual design phase. The current activities in progress include safety analyses, essential research and development, environmental impact statement preparation, and planning efforts in support of line item project start in FY 1995.

In accordance with the Departmental Orders, the Department has the responsibility to perform a safety review of the Advanced Neutron Source. Two options are being evaluated:

1) The Department would conduct a review in accordance with Departmental Orders using the Office of Environment, Safety and Health to perform an independent review augmented with other Departmental resources including assistance from national laboratories and other contractors as needed.

2) The Department would conduct a review using the Nuclear Regulatory Commission to perform an independent safety review.

The Department contacted the Nuclear Regulatory Commission about their possible role in performing the safety review of the Advanced Neutron Source. The Nuclear Regulatory Commission staff was also briefed on the Advanced Neutron Source design and safety analysis in August and October 1993. In a memorandum of March 9, 1994, to the Department, the Nuclear Regulatory Commission indicated that they would respond favorably to a Department of Energy request to perform a safety review. The Nuclear Regulatory Commission envisions that this review would be similar in scope and depth to their review of the Fast Flux Test Facility conducted in the 1970s and that the specific details regarding scope, funding, schedule, and documentation would be established by a memorandum of understanding between the two agencies. The Department will make a decision on the safety review process of the Advanced Neutron Source in FY 1994.

QUESTIONS FROM REPRESENTATIVE SYNAR

Question 5(a): The Department testified that ample operating funds would be provided to Brookhaven National Laboratory to support the upgrade of the Brookhaven Linac Isotope Producer facility (BLIP). Identify the funds in the FY'94 and FY'95 budgets provided specifically for this purpose in particular those for target and radiochemistry development needed to produce isotopes upon completion of the upgraded machine.

Answer: In FY 1994 $6,000,000 of construction funds were appropriated for project 94-E-335, the Brookhaven Linac Isotope Producer Facility Upgrade. These funds were provided to the Laboratory in October 1993. Subsequent assessment by the Laboratory determined that additional funds would be required for new target design studies and for process development research. This requirement was transmitted to the Department in a letter dated February 23, 1994, from Dr. Darrel D. Joel, Chairman, Brookhaven Medical Department. We are currently evaluating this request for funding in Fiscal Years 1994 and 1995. If deemed necessary, these efforts will be funded out of the Biological and Environmental Research program's Medical Applications subprogram. The Department is committed to the successful completion of the upgraded facility and will provide the necessary financial support to assure its success.

QUESTIONS FROM REPRESENTATIVE SYNAR

Question 5(b): Describe the current status of the BLIP upgrade.

Answer: The $6,000,000 construction project to upgrade the Brookhaven Linac Isotope Producer facility at Brookhaven National Laboratory was scheduled to begin on October 1, 1993. Despite a few minor delays, the construction project is very close to being on schedule. To date, the Conduct of Operations requirements have been reviewed and approved by the Laboratory Operation Support Office as well as the National Environmental Policy Act review. Title I preliminary design work which includes the design of the Brookhaven Linac Isotope Producer target cooling and drive systems is nearing completion. Work on the preparation of the Safety Analysis Report is in progress and expected to be completed soon. Title II detailed design work is expected to begin during the third quarter of FY 1994. The project is expected to be completed in June of 1996 as projected.

QUESTION FROM REPRESENTATIVE SYNAR

Question 5(C):

The Department has insisted that its solicitation for the National Biomedical Tracer Facility (NBTF) could not include consideration of federal facilities because the department cannot compete with the private sector pursuant to OMB Circular A-76. Provide a legal memorandum describing the precise application of OMB Circular A-76 to the Department's solicitation for the project definition phase of this facility and how the Department's solicitation is consistent with both Circular A-76 and the Department's procedures and orders implementing Circular A-76.

Answer:

Statements made by the Department of Energy employees that the Department's solicitation for the NBTF Project Definition Studies could not include consideration of national laboratories because the laboratories cannot compete with the private sector pursuant to OMB Circular A-76 were in error. However, it is important that the Department fully address the legal as well as the programmatic issues raised by this question.

OMB Circular No. A-76 (Revised) establishes procedures for determining whether the Government should rely on commercially available sources to provide commercial-type products and services, or should utilize Government employees to provide such products and services. The Circular expresses the policy that the Government should not engage in any activity to provide a commercial product or service if the product or service can be procured more economically from a commercial source. Because the Department is not proposing to do project definition phase studies here with Government employees, the Circular has no application to the Department's solicitation of such studies for the NBTF.

The reason the laboratories were not permitted to conduct Project Definition Studies for the NBTF was based upon the analysis and recommendations of a Business Strategy Group that was formed to plan the activity. This Group was composed of program, procurement, general counsel and controller staff. A major issue respecting the NBTF is whether medical radioisotopes should be produced by the private sector rather than by the Government or by the national laboratories. The Group advised that if the facility is commercially viable, it should be built and operated by the private sector and if necessary, Government assistance should be provided through competitive techniques. The Group also advised that if the facility is not commercially viable, but should be built as a matter of public policy, it appears to fit well within the mission of several of the national laboratories.

In order to determine the commercial feasibility of the NBTF, the Department issued a solicitation for Project Definition Studies which would provide the necessary data. The solicitation was limited to the private sector because that group would be in the best position to provide preliminary analyses regarding commercial feasibility. In addition, the Department was aware of the interests of several organizations in the private sector. The solicitation was issued on October 14, 1993. The North Texas Research Institute and the Universities of Southern California; Purdue; Alabama; and California, Davis were selected to participate in the Project Definition Studies and are currently negotiating with the Department prior to final awarding of the grants. These studies will allow the Department to evaluate the private sector's views of the markets for the isotopes and potential revenues of the NBTF.

The Department has also asked the Institute of Medicine of the National Academy of Sciences to review the NBTF. The capabilities of the national laboratories in the areas of accelerator design, isotope production and distribution, and waste handling are well known to the Department. The data from the Project Definition Studies and the Institute of Medicine report as well as the capabilities of the national laboratories will be considered before any final decisions are made with regard to the NBTF.

QUESTION FROM REPRESENTATIVE SYNAR

Question 5(d): DOE Order 4510.1B, "Economic Assessment of Commercial Activities" requires the Department to prepare a formal A-76 cost comparison study. The Department's witnesses were unable to confirm whether such a study was done. Provide the A-76 study required by DOE 4510.1B. If such a study was not done, explain why.

Answer: An A-76 study of the National Biomedical Tracer Facility, project definition study, was not conducted. Office of Management and Budget policy and DOE internal implementing guidance on A-76 state that it is the policy of the Government to rely on the private sector to supply goods and services when possible. In this case, the Department plans to use the private sector for the project definition study and has issued a solicitation. Therefore, an A-76 study is not needed since the Department has already decided to contract out this activity. It should be noted that if no acceptable proposals are received, other options will be pursued.

The solicitation did not include consideration for Federal facilities to bid on the contract due to the Federal Acquisition Regulations. Section 35.017 of the regulations prohibit Federally Funded Research and Development Centers, including Department of Energy laboratories, from responding to solicitations since they are not permitted to compete with the private sector.

QUESTIONS FROM REPRESENTATIVE SYNAR

Question 5(e):	Provide all responses to the Department's NBTF solicitation.
Answer:	We will be pleased to provide a list of all institutions that have submitted proposals in response to the Project Definition Study announcement. (The information follows:)

INSTITUTIONS RESPONDING TO THE PROJECT DEFINITION STUDY ANNOUNCEMENT

North Texas Research Institute
TRI-X
Pacific Northwest Laboratories
Purdue University
University of Southern California
Biomedical Research Foundation of Northwest Louisiana
The University of Alabama at Birmingham
University of California, Davis
University of New Mexico

QUESTIONS FROM REPRESENTATIVE SYNAR

Question #5f: In your testimony, you committed to providing funding to Brookhaven National Laboratory to allow Brookhaven to provide information on the NBTF project definition. Provide a copy of the written instructions to Brookhaven authorizing this activity and approving the funding. Identify the source of funding and confirmation that funding is available to Brookhaven.

Answer: Since publication of the Project Definition Study announcement to the private sector on October 14, 1993, several private sector institutions as well as National Laboratories have inquired as to the involvement of the laboratories in the preparation of proposals and conduct of the Project Definition Studies. We informed each interested party that laboratory expertise is available to the private sector. Funds will not be provided directly to any National Laboratory for their involvement in the Project Definition Study. However, funding to support National Laboratory involvement in the conduct of the Project Definition Studies has been identified in several of the proposals that include them as subcontractors, and would be provided by the Department through the grantee.

QUESTIONS FROM REPRESENTATIVE SYNAR

Question 5(g): The Department stated that it had received expressions of commercial interest in the NBTF and that is why it was precluded from allowing federal laboratories to apply for a role in the project definition phase based on those expressions of interest. Provide copies of all proposals and other written communications received by the Department from commercial sources expressing an interest in commercial development of the NBTF received prior to the Department's solicitation and identify those upon which the decision to structure the solicitation was based.

Answer: Prior to the release of the National Biomedical Tracer Facility Project Definition Study announcement, the Department was aware of not only commercial interest in building and operating the National Biomedical Tracer Facility such as the North Texas Research Foundation, but also interest from private institutions such as the University of Southern California. This private sector interest in building and operating the National Biomedical Tracer Facility has been expressed publicly (undocumented) at various workshops and Society of Nuclear Medicine business meetings throughout the National Biomedical Tracer Facility development planning process. In fact, the University of North Texas stated at the Purdue National Biomedical Tracer Facility Workshop held April 28-30, 1992, that it could build and operate a high energy machine that would produce medical isotopes. The University of North Texas's interest in building such a facility was again expressed formally to the Department in a letter dated January 24, 1993, to Dr. William Happer and by the University of Southern California in a letter dated March 4, 1993, copies attached. In light of the private sector interest (commercial facilities as well as universities), the Department felt obligated to explore the private sector capability in the National Biomedical Tracer Facility Project Definition Study.

University of North Texas

January 24, 1993

Dr. William Happer
Director, Office of Energy Research
U.S. Department of Energy
Washington, D.C. 20545

Dear Dr. Happer:

For approximately two years, the University of North Texas (UNT) and the North Texas Research Institute (UNT's not-for-profit affiliate) have been developing plans to establish a center along the lines of the proposed National Biomedical Tracer Facility (NBTF). We have spent several hundred thousand dollars in this effort on facility designs, comparative analyses of accelerators, capital costs, operating costs, strategic location, infrastructure, and partnerships with medical institutions. We have also built a liaison with the commercial radiopharmaceutical manufacturers in order to understand their needs and be supportive, rather than competitive. We have been seeking private funding to build the radioisotope production facility with the intent of adding research, training, and education to its mission, once a commercially-viable production facility was in place.

We were delighted to hear that DOE has received a $2 million appropriation for action on the NBTF concept and will be conducting a competition for further development, and ultimately, a site location. UNT and NTRI have established good relationships with industry, the State of Texas, and the private sector to assist the Federal Government and DOE with the funding of this program.

We look forward to receiving and responding to your RFP at the earliest date.

Sincerely,

Rollie Schafer
Associate Vice President for Research
and Dean of the School of Graduate Studies

cc: Mr. Donald E. Erb

Office of the Associate Vice President for Research
and Dean of the Robert B. Toulouse School of Graduate Studies
P.O. Box 5446 • Denton, Texas 76203-5446
817/565-2383 • FAX 817/565-2141 • BITNET: GRADSCH@AAO.UNT.EDU

file

PET IMAGING SCIENCE CENTER
DEPARTMENT OF RADIOLOGY
(213) 342-5940
FAX (213) 342-8778

Called 4/14/93

March 4, 1993

William Happer, Ph.D.
Director, Office of Energy Research
Science and Technical Advisor to the Secretary
Department of Energy
Forrestal Building 7B-058
1000 Independence Avenue, SW.
Washington, D.C. 20585

Dear Dr. Happer:

We in the nuclear medicine community are pleased that the Department of Energy is moving forward with plans for the National Biomedical Tracer Facility (NBTF). It is my understanding that a competitive, public request for proposal (RFP) is forthcoming. We at the University of Southern California, along with our industrial collaborators are very interested in pursuing such a proposal.

If possible, please forward to me a copy of the RFP as soon as it becomes available. Thank you in advance.

Sincerely,

Peter S. Conti, M.D., Ph.D.
Director, PET Imaging Science Center

PSC: dom

1510 SAN PABLO STREET, SUITE 350
[illegible]

QUESTIONS FROM REPRESENTATIVE SYNAR

Question 5(h): Explain why the Department chose to issue grants to institutions to collect the NBTF project definition phase data rather than solicit bids and issue a contract as a normal procurement for architectural and engineering or analytical services.

Answer: The information to be provided in the project definition study reports will be of primary importance to the private sector groups funded to prepare them. Through these grant awards, the private sector will broadly investigate the design of the device, waste disposal issues and isotope distribution, and potential revenues as a part of an overall business plan. The Department, of course, will also use this data to evaluate whether the functions of a National Biomedical Tracer Facility should be performed by the private sector or a Department of Energy National Laboratory. This work is appropriately awarded as a grant. Should the decision be made to build the National Biomedical Tracer Facility, the architect and engineering services would appropriately be solicited using competitive procurement procedures and the award would be made as a contract.

QUESTIONS FROM REPRESENTATIVE TOWNS

Cost of Production

Question 1: In order to establish a viable commercial-scale reactor-isotope production program here in the U.S., what do you estimate it will cost?

Answer: The Department of Energy currently produces as many as 1,100 radioactive and enriched isotopes using two reactors, two large accelerators, electromagnetic separation devices (calutrons), and several smaller facilities at six production sites. The Department is also planning to convert another reactor for the production of molybdenum-99 and related isotopes.

We will provide a revised budget and funding profile when the National Isotope Strategy is provided to Congress.

QUESTIONS FROM REPRESENTATIVE TOWNS

Funding Mechanism

Question 2: Would that cost come out of general revenues: surcharges of some sort, or through some other mechanism?

Answer: Costs to produce isotopes that are sold by the Isotope Production and Distribution Program for commercial or research applications come from a revolving fund established by Public Law 101-101 and are offset by revenues generated by sales of isotope products and services.

The Department of Energy will soon propose a revised funding mechanism for the production and distribution of isotope products and services.

QUESTIONS FROM REPRESENTATIVE TOWNS

Timing

Question 3: How quickly could such a facility be up and running?

Answer: Assuming as an example, the startup of the reactor production of molybdenum-99 and related isotopes, conversion of a small reactor and processing facility for production is expected to take two years.

Representative Towns

Question 4: Where does commercial-scale isotope production fit within the Department of Energy's current new-activity funding priorities?

Answer: Production of radioactive isotopes is a high priority. The Department is developing a National Isotope Strategy, including funding proposals. The plan is near completion and a report will be forwarded to Congress in the near future.

QUESTIONS FROM REPRESENTATIVE TOWNS

Question 5: Has the Department inquired whether there exists sufficient other means of making the research isotopes which would be made using the NBTF?

Answer: The Department is currently funding the National Academy of Sciences, Institute of Medicine to provide an independent evaluation of the priority of the National Biomedical Tracer Facility in light of the clinical and research importance of the isotopes produced, alternative production capabilities, and other nuclear medicine needs. In particular this evaluation will consider upgraded capability at the Brookhaven Linac Isotope Producer.

Appendix ___________

Upon review of the Department's submission, the Subcommittee requested additional information, clarification and corrections concerning DOE's written responses. As of December 1994, the Department has provided only the following additional information. Subsequent submissions in response to the Subcommittee's request are expected to be available for review at the Subcommittee's offices.

Department of Energy
Washington, DC 20585

November 21, 1994

The Honorable Mike Synar
Chairman
Subcommittee on Environment, Energy
and Natural Resources
Committee on Government Operations
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

On December 6, 1993, William H. White, Deputy Secretary of Energy, testified regarding the Department's Isotope Production and Distribution Program.

Enclosed are the answers to three questions that you submitted. The remaining 25 answers are being prepared and will be forwarded to you as expeditiously as possible.

If we can be of further assistance, please have your staff contact our Congressional Hearing Coordinator, Barbara Campbell, on (202) 586-8238.

Very truly yours,

William J. Taylor, III
Assistant Secretary
Congressional and Intergovernmental
Affairs

Enclosures

Printed with soy ink on recycled paper

QUESTIONS FROM REPRESENTATIVE SYNAR

Question 5(d): DOE Order 4510.1B, "Economic Assessment of Commercial Activities," requires the Department to prepare a formal A-76 cost comparison study. The Department's witnesses were unable to confirm whether such a study was done. Provide the A-76 study required by DOE 4510.1B. If such a study was not done, explain why.

Answer: The Department of Energy follows the requirements of Office of Management and Budget Circular A-76. An A-76 study was not conducted for the Biomedical Tracer Facility Project.

As you are aware, the Department's current plan for the Biomedical Tracer Facility is that it provide a mechanism (1) for production of radionuclides for use in medical and industrial applications; (2) for the conduct of research in radioisotope production; and (3) for the providing of opportunities in education and training in isotope production. These principal purposes are for the benefit of the public at large in our desire to spur commercialization of radionuclide production, research, and education and training. The principal purpose is not for the direct benefit of this Department or the Federal government in general.

These purposes require, pursuant to section 5 of Public Law 95-225 that a grant is the appropriate instrument because, as currently planned, we intend the recipient "to accomplish a public purpose of support or stimulation...; and no substantial involvement is anticipated between the executive agency..and the... other recipient during performance of the contemplated activity."

Therefore, the reason that an A-76 study was not performed for the Biomedical Tracer Facility is that such studies are not required for assistance arrangements under any circumstance.

QUESTIONS FROM REPRESENTATIVE SYNAR

Question 5(e): Provide all responses to the Department's NBTF solicitation.

Answer: In response to Chairman Synar's letter of April 8, 1994, the Department provided all materials associated with the National Biomedical Tracer Facility Project Definition Study announcement, review, and awards. The transmittal letters are attached.

The Deputy Secretary of Energy
Washington, DC 20585
April 28, 1994

The Honorable Mike Synar
Chairman, Subcommittee on Environment,
Energy, and Natural Resources
Committee on Government Operations
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your letter of April 8, 1994. We are in the process of gathering the information you requested relating to the National Biomedical Tracer Facility/Project Definition Phase Study panel review.

We regret that we were unable to provide the information to you by April 15, 1994; however, the Department is committed to being as responsive to your request as possible. Our intent is to forward this information to you no later than May 10, 1994.

Thank you for your interest in the National Biomedical Tracer Facility/Project Definition Study.

Sincerely,

Bill White

Bill White

cc: The Honorable William F. Clinger, Jr.
Ranking Minority Member
Committee on Government Operations

The Honorable J. Dennis Hastert
Ranking Minority Member
Subcommittee on Environment, Energy,
and Natural Resources

The Deputy Secretary of Energy
Washington, DC 20585

May 3, 1994

The Honorable Mike Synar
Chairman, Subcommittee on Environment,
Energy, and Natural Resources
Committee on Government Operations
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This is in reply to your letter of April 8, 1994, concerning the National Biomedical Tracer Facility and project definition study. Your concerns are being addressed and fully considered in any actions taken by the Department. You have received answers to many of the questions in your March 4, 1994 letter. The Department is developing answers to the remaining questions which we expect to deliver by May 27, 1994.

We have enclosed the following information in response to your April 8, 1994, letter:

- The charter and membership of the National Biomedical Tracer Facility review panel, as well as the completed conflict of interest forms for each member (Enclosure 1).
- All briefing materials prepared and/or presented by the Department for the review panel (Enclosure 2).
- All analyses, evaluations, critiques, minutes, notes, rankings, ratings, summaries of panel reviews, recommendations, and other records or products prepared by members of the review panel related to the National Biomedical Tracer Facility proposals (Enclosure 3).
- All analyses, evaluations, critiques, minutes, notes, rankings, ratings, summaries of panel reviews, recommendations of award, grant awards, and other records or products prepared by the Department in its review of the National Biomedical Tracer Facility proposals and award of the National Biomedical Tracer Facility project definition study grants (Enclosure 4). Additional information will be provided at the time the awards are made.
- All responses to the Department of Energy National Biomedical Tracer Facility solicitation (Enclosure 5).

- You inquired as to the reason the Department instructed the panel members to return some proposals and to destroy others after completion of the panel review, and requested copies of the relevant Departmental orders and procedures governing such activities. The policy that governs this area of Departmental activity is contained in the Code of Federal Regulations, 10-600.16 (i), "Outside Reviews" (excerpt in Enclosure 6). The normal practice of the Department is for reviewers to return all proposals. However, because the volume of the proposals sent to each reviewer was so large, we requested that the reviewers return only those proposals that contained proprietary information and to destroy the other proposals.

Some of the information contained in the enclosed documents may be exempt from public disclosure pursuant to exemptions of the Freedom of Information Act, including Exemptions 4, 5, and 6; 5 U.S.C. 552(b)(4), (b)(5), and (b)(6). Exemption 4 protects confidential trade secrets and commercial or financial information obtained from a person. Exemption 5 protects memoranda or letters that contain advice, opinions, or recommendations that are pre-decisional and a part of the decision-making process of the agency. Exemption 6 protects information in personnel, medical, and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. We request, therefore, that special care be taken to protect the confidentiality of these records, and that you consult with the Department prior to making any decision regarding disclosure.

Please let us know if you or your staff need additional information.

Sincerely,

Bill White

Bill White

Enclosures

cc: The Honorable William F. Clinger, Jr.
Ranking Minority Member
Committee on Government Operations

The Honorable J. Dennis Hastert
Ranking Minority Member
Subcommittee on Environment,
Energy, and Natural Resources
Committee on Government Operations

QUESTIONS FROM REPRESENTATIVE SYNAR

Question 5(f): In your testimony, you committed to providing funding to Brookhaven National Laboratory to allow Brookhaven to provide information on the NBTF project definition. Provide a copy of the written instructions to Brookhaven authorizing this activity and approving the funding. Identify the source of funding and confirmation that funding is available to Brookhaven.

Answer: Since publication of the Project Definition Study announcement to the private sector on October 14, 1993, several private sector institutions as well as National Laboratories have inquired as to the involvement of the laboratories in the preparation of proposals and conduct of the Project Definition Studies. We informed each interested party that laboratory expertise is available to the private sector. Funds will not be provided directly to any National Laboratory for their involvement in the Project Definition Study. However, funding to support National Laboratory involvement in the conduct of the Project Definition Studies has been identified in several of the proposals that include them as subcontracters, and would be provided by the Department through the grantee. In addition, the Department has also provided $25,000 in FY 94 funds to Brookhaven to begin examining the feasibility of further upgrading the BLIP facility (see attached documentation).

The Deputy Secretary of Energy
Washington, DC 20585

July 21, 1994

The Honorable Mike Synar
Chairman, Subcommittee on Environment,
Energy, and Natural Resources
Committee on Government Operations
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

As promised in my May 3, 1994, letter, enclosed is the remainder of the information you requested concerning the awards for the National Biomedical Tracer Facility Project Definition Study. These awards were recently released by the Department. The enclosure contains the field office procurement package for each of the National Biomedical Tracer Facility Project Definition Study awardees and the letter of rejection for the non-awardees.

The enclosure to this letter completes the information you requested in your letter of April 8, 1994. Please let us know if you or your staff require further information concerning the Project Definition Study awards.

Sincerely,

Bill White

Bill White

Enclosure

cc: The Honorable William F. Clinger, Jr.
Ranking Minority Member
Committee on Government Operations

The Honorable J. Dennis Hastert
Ranking Minority Member
Subcommittee on Environment,
Energy, and Natural Resources
Committee on Government Operations

ER-63

FY 1994 Programmatic Guidance

Cherri Langenfeld, Manager
Chicago Operations Office

Following is programmatic guidance for the Biological and Environmental Research program prepared to be commensurate with changes in the FY 1994 August Approved Funding Program for Operating Expenses.

	B/A	B/O
Brookhaven National Laboratory		
KP0202 Funds are being provided to support shiptime for the ocean margins program ($26,000 B/A and B/O); and for the ocean margins program site review and contractors' meeting ($82,000 B/A and $42,000 B/O).	$+ 108,000	$+ 68,000
KP0401 Funds are being provided for the protein data bank to support collaborative software with Columbia University.	+ 250,000	+ 50,000
KP05 Supplemental funds are being provided for the free air carbon dioxide enrichment (FACE) facility development.	+ 28,000	+ 28,000
KP0601 Funds are being provided to examine the feasibility of further upgrading of the Brookhaven Linac Isotope Producer (BLIP).	+ 25,000	+ 25,000

The revised Work Authorization reflecting these changes is attached.

If you should have any questions, please do not hesitate to call me or members of my staff.

Ari Patrinos
Acting Associate Director for Health
and Environmental Research
Office of Energy Research

Attachment

cc: G. F. Giarrante, CH
N. P. Samios, BNL (w/o attachment)
D. Robbins, BNL (w/o attachment)
R. Gordon, BAO
bcc: M. Riches, ER-74
D. Smith, ER-72
D. Smith, ER-73
ER-63:NBurdette 3-3129

ER-63	ER-63	ER-63	ER-63	ER-70	ER-70
NBurdette 8/ /94	MOsinski 8/ /94	ILinger 8/ /94	RDeLorenzo 8/ /94	JWooley 8/ /94	APatrinos 8/ /94

Department of Energy
Washington, DC 20585

December 5, 1994

The Honorable Mike Synar
Chairman
Subcommittee on Environment, Energy
and Natural Resources
Committee on Government Operations
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

On November 21, 1994, we sent you the answers to three questions from the December 6, 1993 hearing.

Enclosed is the answer to one question that you submitted. The remaining 24 answers are being prepared and will be forwarded to you as expeditiously as possible.

If we can be of further assistance, please have your staff contact our Congressional Hearing Coordinator, Barbara Campbell, on (202) 586-8238.

Very truly yours,

William J. Taylor III
Assistant Secretary
Congressional and Intergovernmental
Affairs

Enclosure

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QUESTIONS FROM REPRESENTATIVE SYNAR

Question 5(a):	The Department testified that ample operating funds would be provided to Brookhaven National Laboratory to support the upgrade of the Brookhaven Linac Isotope Producer facility (BLIP). Identify the funds in the FY 94 and FY 95 budgets provided specifically for this purpose in particular those for target and radiochemistry development needed to produce isotopes upon completion of the upgraded machine.
Answer:	In FY 1994, $5,821,000 of construction funds were appropriated for project 94-E-335, the Brookhaven Linac Isotope Producer Facility Upgrade. These funds were provided to the Laboratory in October 1993. Subsequent assessment by the Laboratory determined that additional funds would be required for new target design studies and for process development research. This requirement was transmitted to the Department in a letter dated February 23, 1994, from Dr. Darrel D. Joel, Chairman, Brookhaven Medical Department. In response to this request, the Department has provided $136,000 in FY 1994 funds to develop new target designs for the upgraded BLIP facility. The Department plans to continue support for this activity in FY 1995.

MAY 2 1994

Energy Research

FY 1994 Programmatic Guidance

Cherri Langenfeld, Manager
Chicago Operations Office

Following is programmatic guidance for the Biological and Environmental Research program prepared to be commensurate with changes in the FY 1994 May Approved Funding Program for Operating Expenses.

	B/A	B/O
Brookhaven National Laboratory		
KP0201 Funds are being provided to initiate a project on field studies in atmospheric chemistry under the direction of P. H. Daum.	$+ 400,000	$+ 400,000
KP0401 Additional funds are being provided to begin development of a dictionary for NMR structural data compatible with the crystallographic dictionary under a subcontract with the Protein Data Bank.	+ 100,000	+ 100,000
KP0601 Funds are being provided to increase the epithermal neutron flux and to improve the overall quality of the neutron beam of the BMRR for use in clinical BNCT ($300,000), and for additional targetry research and development in support of the BLIP Upgrade Project ($136,000).	+ 436,000	+ 436,000

The revised Work Authorization reflecting these changes is attached.

If you should have any questions, please do not hesitate to call me or members of my staff.

Signed by

Ari Patrinos
Acting Associate Director for Health
and Environmental Research
Office of Energy Research

Attachment

cc: G. F. Giarrante, CH
N. Samios, BNL (w/o attachment)
D. Robbins, BNL (w/o attachment)
R. Gordon, BAO (w/o attachment)

BROOKHAVEN NATIONAL LABORATORY
ASSOCIATED UNIVERSITIES, INC.

P.O. Box 5000
Upton New York 11973-5000
TEL (516) 282-3603
FAX (516) 282-5260
E-MAIL

Medical Department

February 23, 1994

Dr. Robert Wood
Director, Medical Applications & Biophysical Research Division
Office of Health & Environmental Research, ER-73
Washington, DC 20585

Dear Dr. Wood;

As we discussed during our meeting on January 5, there is a pressing need for additional research and development (R&D) in support of the BLIP Upgrade Project. The $6M line item is basically for construction. Funds for associated research, development, and capital equipment needs were not requested since they were considered inappropriate as part of a construction project. These needs are distinct from those that will eventually be required to operate the BLIP/LINAC and processing facility following completion of the project. Clearly, our staff in the Radionuclide & Radiopharmaceutical Research Program (R&RR) cannot accomplish the research and production goals indicated in FWPs in view of the effort being expended to successfully execute the BLIP Upgrade Project. To adequately reduce this burden, we need a Ph.D. nuclear chemist, an engineer, and a radiochemistry technician. Further, in order to assume production of radionuclides unique to LAMPF, an additional Ph.D. radioanalytical chemist, and a radiochemistry technician will be required.

The BLIP Upgrade Project includes $565K for engineering and design of modifications needed at Building 801 (the Hot Laboratory), Building 930 (Linac), and Building 931A/B (BLIP). The bulk of this money, $417K, is for the Linac. The remainder is to support engineering for BLIP and the Hot Lab from predominately outside sources. There is no support for R&D. We have found that there is a substantial burden on our staff to educate, guide, provide data and coordinate with outside engineers so that their efforts are compatible with the existing systems. For example, extensive radiation shielding calculations performed by R&RR staff were needed in order to guide new hot cell design by an outside firm. Only our staff have the knowledge of the operating radiation environment. Considerable R&RR staff time was also needed to explain to vendors the software and hardware requirements of a new BLIP computer control system. There are many other examples of the need of program personnel to continuously participate in this fashion. As the Project moves forward this burden will only increase. Therefore, there is an immediate need for an engineer to coordinate and assist the technical design work. This engineer will continue to assist with the operation of the facility following its completion.

A major problem caused by the higher beam intensity in the upgrade (145 μA vs ~50 μA now), is the severe thermal load on the production targets. Although the need to construct a more efficient cooling system was foreseen and is included in the Upgrade Project, our preliminary theoretical calculations predict that at 145 μA the central temperatures of the Zn (for ^{67}Cu) and RbCl (for ^{82}Sr) targets will substantially exceed the boiling points of these materials even with enhanced water flow. New and more sophisticated target designs that dissipate heat faster from their center to the cooling interfaces are required. Test targets must be built and thermal behavior in beam measured. This type of research is not accommodated in the construction budget. A Ph.D. nuclear chemist is needed for targetry research and experimentation, which must begin now for BLIP to go on-line in 1996.

Upon completion of construction, we will be able to process more intensely radioactive targets. However, there will be a need to increase the frequency of production runs. It is, therefore, essential to speed up isotope processing, which includes set-up and clean-up, as well as the actual chemical separation. Process development research, up to and including automation, needs to begin in order to be ready for the large work load anticipated in 1996 and beyond. An additional radiochemistry technician, working under the supervision of the nuclear chemist described above, is thus required.

It may become necessary for us to assume the isotope production burden resulting from the closing of LAMPF in FY 1996. To this end we must learn to produce several large volume isotopes that are unique to LAMPF (e.g., ^{88}Y, ^{22}Na, ^{109}Cd, ^{73}As). In general, we cannot simply adopt LAMPF production methods. Again, the existing staff, does not have the time to perform this research. It will, therefore, be impossible to provide these four extra isotopes without a radioanalytical chemist and a supporting technician.

Finally, we have various capital equipment needs related to operating an enhanced production mission that were not included in the construction project. Most of this apparatus is analytical instrumentation to characterize the chemical purity of isotopes. In particular, an inductive coupled plasma mass spectrometer (ICP-MS) is needed both during the development phases and routine isotope production. We are the only radionuclide production group that does not have an ICP-MS and/or other comparable instrumentation. The sensitivity, and speed of analysis and flexibility of this device is unsurpassed, and we must acquire one in order to carry out the required analyses.

The personnel and equipment budgets are attached. The requested staff would all have continuing roles with BLIP operations after the completion of the construction project. We understand that the operating costs for year-round running of the upgraded BLIP will be considered later.

I fully realize this is a request for substantial amounts of money from an already tight budget. The estimates are, however, not exaggerated if we are to meet production expectations starting in 1996. If you have questions or need further information, I, Dr. Leonard F. Mausner and Dr. Suresh C. Srivastava will be glad to help. Thank you for your consideration.

Sincerely,

Darrel D. Joel, D.V.M., Ph.D.
Chairman

DDJ:gmg

cc: D. J. Robbins
R. B. Setlow

2/94 BUDGET

ADDITIONAL EXPENSES FOR LAMPF REPLACEMENT

SALARY (5% ESCALATION)		EFFORT			BASE	(THOUSANDS OF DOLLARS)	
		FY94	FY95	FY96	FY94	FY94	FY95
RADIO ANALY ENGINEER	ASSOC SCI	0.00	1.00	1.00	53	0	55
RADIO CHEM TECH	RES ASSOC	0.00	1.00	1.00	41	0	43
TOTAL		0.00	2.00	2.00		0	98
Fringe	0.34	0.35	0.36			0	34
MSTC						0	40
Material Handling Burden							5
SUBTOTAL DIRECT COSTS:						0	177
Electric Power	0.087 direct Labor cost					0	12
Dept ADM	0.3530 direct Labor cost					0	47
SUBTOTAL DIRECT & ALLOCATED COSTS:						0	236
Laboratory G&A 40.3%, 43.5%						0	102
TOTAL COST						0	338

2/94 BUDGET

BROOKHAVEN ADDITIONAL COSTS
BR BLIP UPGRADE COSTS

SALARY (5% ESCALATION)			EFFORT FY94	EFFORT FY95	EFFORT FY96	BASE FY94	(THOUSANDS OF DOLLARS) FY94	(THOUSANDS OF DOLLARS) FY95
NUCLEAR CHEMIST PHD,	ASST SCI		0.25	1.00	1.00	49	13	52
ENGINEER	ASSOC SCI		0.25	1.00	1.00	53	14	55
RADIO CHEM TECH	RES ASSOC		0.25	1.00	1.00	41	11	43
TOTAL			0.75	3.00	3.00		37	150
Fringe		0.34	0.35	0.36			13	52
MSTC							20	40
Material Handling Burden								5
SUBTOTAL DIRECT COSTS:							70	247
Electric Power	0.087 direct labor cost						4	18
Dept ADM	0.3550 direct labor cost						18	72
SUBTOTAL DIRECT & ALLOCATED COSTS:							92	337
Laboratory G&A 49.5%, .43.5%							44	145
TOTAL COST							136	482

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